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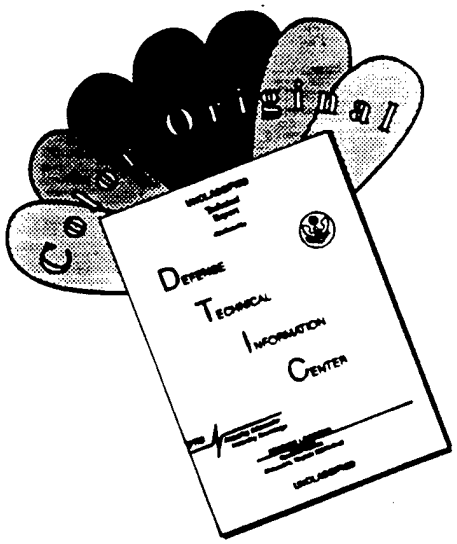

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The second year of the Project has been an implementation year. The goals for this year, as outlined in the Statement of Work (Proposal page 18) include: 1) implementing data collection procedures at mammography facilities in the state, including equipping, training and monitoring staff at mammography facilities and equipping and monitoring cancer registrars; 2) beginning data analyses and feedback, including finalizing data collection procedures and preparing quarterly reports for participating physicians and facilities. We have been successful in achieving the above-stated goals. The specific details of our progress are outlined in this report.

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INTRODUCTION

The long-term objective of this Project is to improve the health of New Hampshire women by improving breast cancer screening and detection. To accomplish this, the New Hampshire Mammography Network is implementing a comprehensive database tracking system, which allows us to follow the outcomes of women receiving mammography (either diagnostic or screening) and other breast procedures (excisional or core stereotactic biopsy or fine needle aspiration) over time. We are linking demographic and risk factor information we obtain from women with radiologists' and pathologists' reports. For individuals who are diagnosed with breast cancer, we are linking their data with the NH State Cancer Registry to obtain outcomes through first course of treatment and vital statistics data to match cases with morbidity data.

New Hampshire (N.H.) is well suited to this type of population-based research. It has a stable population with a blend of urban and rural communities and has a relatively high level of literacy (82.2% of New Hampshire adults are high school graduates), which simplifies interviewing and form completion. New Hampshire is also a relatively small state with an estimated population of 1,136,000 (1). Breast cancer is the leading cancer in N.H. women with over 800 cases per year, representing 33% of all female cancers (2). The mortality rate is 29 per 100,000, which is higher than the national rate of 27.3 per 100,000 (3). Women between the ages of 40 and 74 represent about 14% of the populationof 160,000 (1). Data from 1991 on the behavioral risk factors of N.H. women revealed that 37% of women between the ages of 40-49 report that they have not had a mammogram within the past two years and 50% of women over age 50 report that they have not had a mammogram within the past year (4). Clearly, the development of a population-based mammography registry is an important contribution to understanding the problem of breast cancer in New Hampshire.

While the first year of the Project was a development and design year, the second year has been an implementation year. The goals for this year, as outlined in the Statement of Work (Proposal page 18) include: 1) implementing data collection procedures at mammography facilities in the state, including equipping, training and monitoring staff at mammography facilities and equipping and monitoring cancer registrars; 2) beginning data analysis and feedback, including finalizing data collection procedures and preparing quarterly reports for participating physicians and facilities. We received funding from the Centers for Disease Control in January 1996 to conduct a quality assurance project on the diagnostic acumen of breast pathology. A preliminary summary of the project is described under the section entitled, "NHMN Related Studies Currently in Progress" (pg. 9). That project is nearing completion, and a proposal for additional funding has been drafted for a continuation into 1997 (See Appendix A). We will address in the Methods and Materials section of this report the progress we have made in accomplishing these

tasks in three sections: Project Implementation and Start-up, Data Analysis and Feedback Reporting Procedures, and NHMN Related Studies Currently in Progress.

METHODS AND MATERIALS

• Project Implementation and Start-up

Our pilot phase came to an end in the Spring of 1996. On April 1 1996, we completed our final round of reliability testing of all project forms (See Appendices B and C) and ended the design testing phase for data management and linking. A high-speed double-headed scanner was purchased for the bulk of data entry. We anticipate needing to process approximately 2,000 packets of data per week. Patient, provider and facility identifiers are double-entered by hand and linked using bar code technology and scanning. We are using this technology for assigning data to files and for up-sequencing of multiple visits to one data file so that we may track mammographic occurrences by breast, woman, and facility and by radiologist interpretation. We have designed all the training materials for mammography facilities and the quality assurance systems for data checking. Four field coordinators (2 permanent and 2 temporary) were hired and trained, and all mammography facilities have received at least one and in most cases several implementation visits by one of more of these coordinators.

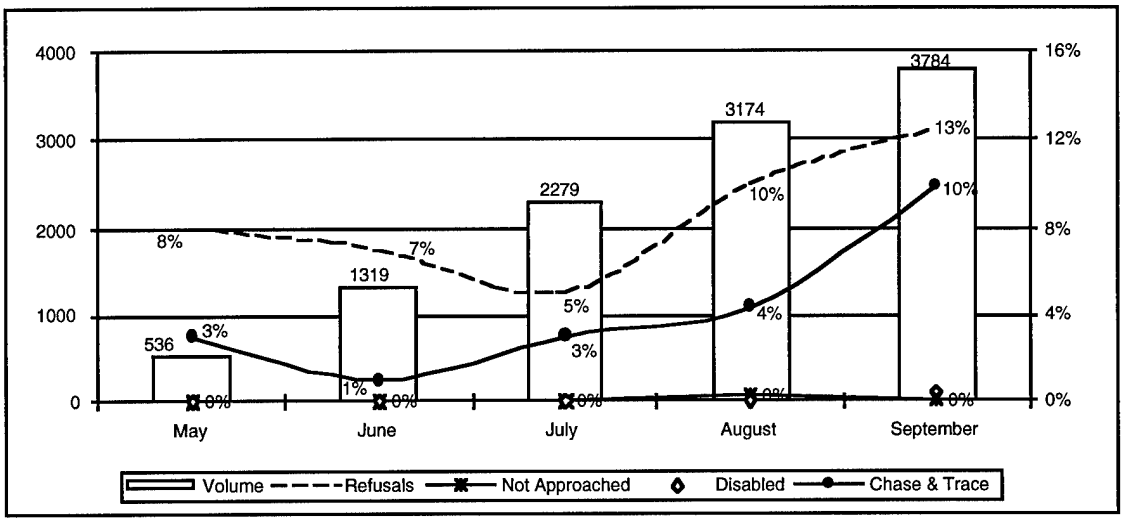
To date (October 28th) 36 of New Hampshire's 46 mammography facilities are contributing data to the NHMN. Five of the remaining facilities have decided to use computer systems for mammography data collection, which is still in development. We are contracting with Insight™, a computerized mammography management system, to customize data entry screens to match our paper forms (See Appendix C). We will then be able to take data downloads from them on a quarterly basis. Women participants will continue to sign and complete the General Information Form (Appendix B), which will be scanned at the Project office. Two of the remaining facilities are on hold pending their own institutional review board approval. This process has taken much longer than expected because these hospitals were purchased by a large corporate health care management company and are in administrative transition. We expect the transition will be complete by January 1 and that the project will receive institutional review board approval shortly thereafter. One mammography facility is currently not accredited to perform mammography, but will obtain new mammography equipment by the end of the year, will go through accreditation, and then will begin providing data to the project. The remaining two facilities have asked to delay implementation until some staff transitions have taken place. We hope to have all facilities contributing data by the Spring of 1997.

An additional goal for Year 2 was to monitor the status of mammography facilities in their contribution of data to the project. Each facility receives a status report at approximately 60-day intervals that reveals the total volume of mammograms done at that facility, the number of women refusing to take part in

the project, the number of women not approached due to scheduling or other problems, and the amount of essential information that has not been received from that site with comparisons with the aggregate of other facilities contributing data. These status reports are critical in assisting the facilities to follow-up on missing data and in identifying problem areas in the process of data collection for correction. Appendix D contains a sample status report used for this purpose. Upon receipt of the status reports, facilities are entered into our system for follow-up of missing data (Called our "Chase and Trace" System). Forms that are missing essential information are photocopied onto bright pink paper and are returned to the facility for completion or correction. The implementation of this system has resulted in improved completion rates on data forms at the first point of submission.

Figure 2 outlines the overall volume of mammographic encounters in the database, the refusal rate, the number of disabled individuals who could not take part due to their disability, and the number not approached since the pilot phase ended and actual data entry began (May 1 1996).

Figure 2 Volume and Status of the NHMN Database May 1 - September 16 (n=27 facilities).



From May 1 through September 16, 11,092 mammographic encounters have been entered into the database. The majority of women in the database are over age 50 (55%) and 45% are under age 50. We have found that the first four to six weeks represents a start-up phase where the data collection process can be unstable. Refusal and not-approached rates are higher, as are rates of missing essential information. Once the process has become more incorporated into a facility's routine, the refusal rates drop to between 6% and 8%, not-approached drops to virtually zero, and missing-essential-information rates drop to approximately 3 to 5%. The status reports have been enormously helpful in improving the completeness of data that are submited to the Project.

Because the accuracy of data is so critical to the research conducted using NHMN data, we have incorporated several quality assurance measures into the process of data collection. First, the scanning technology we are using to process project forms has set parameters for acceptance or rejection of data. For example, if a woman indicates she has no breast concerns on the Patient Intake Form but goes on to describe a breast lump, the form will be kicked out of the scanner for visual inspection and verification. Staff operating the verification station for the scanner have been trained on all parameters for verification. Second, the patient registration system (where patient identifiers are double-entered) automatically selects cases (10% of cases are selected at random, based on volume of mammographic encounter for each facility) for radiologist report quality assurance. For the selected cases, consent forms are copied and facilities pull the radiologist reports. The field coordinators review the text reports and complete a corresponding radiologist form. These forms are then compared with the reports submitted by the participating radiologists, and discrepancies are reviewed by our radiologist liaison. To date, there is a 96% agreement between the field coordinators' interpretation of the text reports and their completed radiologist reports, indicating that radiologists are completing their forms correctly. Our radiology liaison follows up with any radiologist using an incorrect format in completing data forms.

In our original proposal, we planned to contract with tumor registrars to abstract breast pathology reports at New Hampshire labs. In part, because of the funding we received for the N.H. Quality Assurance Project, the labs are sending their pathology reports to our Project office and they are abstracted on-site. Our pathology interpretation form is included in Appendix E. Quality assurance is performed by our pathology liaison (a pathologist at Dartmouth-Hitchcock Medical Center) on 25% of the abstracted pathology reports, with greater than 94% agreement between the pathology liaison and the abstractor. Our institutional review board has given us permission to hold identifiers from breast tissue reports for six months, to allow for adequate matching with the NHMN. When this six-month period passes, identifiers are dropped from the database and anonymous data remains. We have developed and tested our matching protocols with the N.H. State Tumor Registry and are able to perform the linkages between women in the NHMN and the breast pathology database.

As of October 15, 109 cases (by individual) have been matched between the NHMN and the breast pathology database. On the individual level, over time (e.g., the most severe diagnosis for that person, regardless of time sequence), this translates into seven unsatisfactory cases (needs repeat biopsy), 77 benign cases, one highly suspicious case and 27 malignant cases.

Table 1 (next page) outlines the Indications for these exams and the pathology outcomes.

Table 1 **Mammographic Indication and Breast Pathology Outcomes for Matched Cases in the NHMN and Breast Pathology Databases.**

Indication	Pathology Outcome
Baseline, Screening, or Screening Plus Additional Views (n= 64)	Benign = 45 Malignant = 16 Unsatisfactory = 3
Diagnostic, Follow-up, or Additional Views to Supplement Recent Exams (n=42)	Benign = 30 Malignant = 8 Unsatisfactory = 4

Creation of the database, data management processes (for paper system), and data linking for analyses have all been accomplished. Our further challenges include completing the design and implementation of computer systems for data collection and designing the interfaces between the facilities that use them and our master database. We anticipate having the entire process completed by next summer 1997. A published paper and accompanying commentary about the development and design of the NHMN are included in Appendix G.

- **Data Analysis and Feedback Reporting Procedures**

The second technical objective of our proposal is to evaluate the impact of reporting performance measures on radiologists' diagnostic acumen. The following definitions have been agreed upon by our research team for purposes of conducting these analyses.

1) Screening Mammogram - This is a mammogram whose occurrence is not influenced by concerns about the presence of symptoms, positive clinical breast exam, or prior mammogram one year ago.

2) Positive Screening Mammogram Interpretation - A screening interpretation will be considered positive: 1) if the American College of Radiology (ACR) Lexicon Code is 0 (assessment incomplete), 4 (suspicious abnormality), or 5 (highly suggestive of malignancy) OR 2) any screening mammogram interpretation (ACR Lexicon Code of 0-5) that is accompanied by recommended follow-up for any additional work-up. In practice settings where the ACR code is determined only by using information beyond the initial screening mammogram, the screening mammogram will be interpreted as ACR code = 0 if there is any additional work-up performed beyond the screening mammogram.

3) Negative Screening Mammogram Interpretation - A screening interpretation will be considered negative if the ACR code is 1 (negative) or 2 (benign finding, negative) AND the recommended follow-up for routine mammogram is one year or longer.

4) Positive/Negative Screening Mammogram Interpretation - A screening interpretation will be considered positive in the first analysis, and then negative in a repeated analysis if the ACR code is 3 (probably benign finding) AND the recommended follow-up is for less than one year.

5) Cancer Diagnosis - An outcome is defined as cancer (or positive) if there is a histologic proved diagnosis of DCIS or invasive cancer, or registry documentation for cancer within the follow-up period.

6) Non-Cancer Diagnosis - An outcome is defined as non-cancer (or negative) if there is a proved benign diagnosis or no pathology at the end of the follow-up period (one or two years).

7) Follow-up Time - One Year - The one-year analysis will be based on a time period of 12 months time period from the date of the index mammogram. Twelve months is intended to be a calendar year (e.g., January 1995 - December 1995). The index mammogram is a screening mammogram that begins the follow-up period.

8) Follow-up Time - Two Years - The two-year analysis will be based on a time period of 24 months time period from the date of the index mammogram. For the two-year analysis, two years would be substituted for one year in the analyses below (Item 10).

9) Accuracy Indicators

a) Positive Screen Mammogram, True Positive (TP), and False Positive (FP) - A positive screening mammogram is a true positive if there is a cancer diagnosis (date of diagnosis will be used for time period indicator) before the end of the follow-up period. This is regardless of the mode of detection. A positive screening mammogram interpretation is a false positive if there is no cancer diagnosis (date of diagnosis will be used for time period indicator) before the end of the follow-up period.

b) Negative Screen Mammogram, True Negative (TN), and False Negative (FN) - A negative screening mammogram interpretation is a true negative if there is no cancer diagnosis before the end of the follow-up period. A negative screening mammogram interpretation is false negative if there is a cancer diagnosis date before the end of the follow-up period.

10) Analyses

a) Screening Interpretation Only - The initial analysis will be for screened mammograms only. In order to include all women in the analysis, women having had additional evaluations at the time of the index mammogram will be included. The mammogram interpretation for these women would be considered as ACR "0" for this analysis.

b) Screening Plus Additional Evaluation Interpretation (Screen-Plus) - The second analysis will be for screening mammography plus further diagnostic work-up. For this analysis, we would use the ACR codes assigned at the end of the complete workup process, including all radiologic studies up to, but not including, biopsy for all women.

Table 2 Illustrates the indices for calculating accuracy

Table 2 Indices for Calculating Accuracy

Mammography Result	Cancer Status* Positive	Negative	
Mammo +	TP	FP	Total Test +
Mammo -	FN	TN	Total test -
Total	Women with cancer	Women without cancer	

Sensitivity = TP/TP + FN
Specificity = TN/FP + TN
Positive Predictive Value = TP/TP +FP
Negative Predictive Value = TN/FN +TN

* A histologically or registry proved ductal carcinoma in situ or invasive primary cancer of the breast. Lobular carcinoma in situ will be included in one analysis, then removed for a second analysis.

We have developed our report formats and are in the process of having N.H. radiologists review and approve of the report formats (draft reports are included in Appendix F). Any report that contains patient-level information will be treated as confidentially as any medical record. Dummy codes will be generated each time a report is created to protect the identity of a receiving facility or radiologist. These codes will never be able to link participants to actual study identifiers. We are currently monitoring rates of case outcomes as they are submitted to the NHMN.

Additional Analysis Strategies - In addition to the accuracy indices, a receiver operating characteristic (ROC) curve regression analysis will be conducted. The ROC will be a spin-off of the calculation of sensitivity and specificity, requiring the same definitions. The regression ROC will enable us to compare individual ROC curves while controlling for other variables. We do anticipate that we will have to collect data for a period of at least two years to obtain stable enough rates of sensitivity and specificity at the provider level to conduct the ROC regression analysis. The research team is currently devising the specific methods for conducting these analyses.

• NHMN Related Studies Currently in Progress

The New Hampshire Breast Pathology Quality Assurance Study was funded by the New Hampshire Division of Public Health Services through a cooperative agreement with the Centers for Disease Control (grant # U57-CCU108362-02). Its purpose is to evaluate the diagnostic accuracy and completeness of information provided in breast surgical pathology reports and to improve agreement on breast pathology by designing and implementing a standardized breast pathology checklist agreed upon by N.H. pathologists. We have been working with pathologists in NH to design the checklist of diagnostic core variables for breast pathology reports, based on nationally established criteria (5-8) that will be used to improve breast pathology agreement. In addition, we are exploring the degree to which any diagnostic variability is associated with sample sources, specimen evaluation, or slide preparation.

The study's pathology liaison visited each pathology lab in the state. Pathologist eligibility requirements included interpreting breast tissue pathology in a NH practice and not relocating practice or retiring within the study time period (one year). We obtained Institutional Review Board approval to maintain an anonymous database on breast pathology (where patients whose breast tissue has been sent to the registry are not identified without their consent), and active consenting participation from N.H. pathologists. The QA Study was described in detail in subsequent letters and fact sheets and informed consent was obtained from all pathologists willing to participate. All participating pathologists were then asked to complete a survey detailing demographic and practice characteristics.

At each participating institution, a designated pathologist or laboratory assistant was asked to make copies of all breast tissue reports (including fine needle aspirates) and submit them, in batched quantities, to the study center. Breast tissue reports were collected for a three-month period to assess current contents of breast pathology reports. These were abstracted by a research associate and entered into the pathology relational database for analysis.

Database Design, Data Entry, and Quality Assurance

A relational database was designed to record information from breast pathology reports as they are submitted. The database was developed by the study's pathology liaison and pathology coordinator, using the core variables designated by the National Cancer Institute Sponsored Breast Cancer Surveillance Consortium and other information commonly included in pathology reports in New Hampshire. To maintain confidentiality, no identifying information is included in the database. Each patient, pathologist, and lab is assigned a unique ID that is used for the purposes of linking and tracking data.

Data collected in the pathology database include: data links (anonymous and unique patient ID, patient's date of birth and gender); site information (lab code, pathologist code); case information (date of procedure, case number, type of procedure and laterality, physician, history of previous biopsies); diagnostic information (includes a number of categories for both benign and malignant conditions, as well as prognostic indicators such as SBR grade and ER/PR status).

In the initial stages of database design and data collection, information from submitted pathology reports was transcribed onto a standard paper form and reviewed for accuracy by the pathology liaison prior to entry into the pathology database. When the format of the database stabilized, a transition was made to entering data directly into the computer from the pathology reports.
To evaluate the accuracy of information extraction from the reports and data entry, 20 records from every batch of 100 sequentially entered in the database are randomly selected for review by the pathology liaison.

After this three-month period was complete, two additional surveys were mailed to participating pathologists. One ascertained which diagnostic criteria pathologists felt should routinely appear in a breast pathology report. The second, sent to one designated pathologist at each laboratory, ascertained specimen sources and methods of preparation and processing. Data from the three surveys and the breast tissue reports were entered and analyzed using descriptive statistics.

- What We've Learned

We learned that 44 pathologists interpret breast pathology in New Hampshire and are eligible to take part in the Project. Of these, 35 (79%) agreed to participate. Seventeen of the state's 26 hospitals have laboratories where breast specimens are read; 14 (82%) are participating. Ten hospitals have labs that cut slides; 8 (80%) are participating. The demographic/practice characteristics survey and the report content survey were completed by 91% and 94% of participating pathologists, respectively. The survey on specimen preparation was completed by 83% of designated pathologists, representing the 12 participating labs where breast slides are cut.

Characteristics of Pathologists

New Hampshire pathologists range in age from 31 to 60 with a mean age of 47 (S.D.=8.0 years). The majority are male (72%). The mean year of graduation from medical school was 1976 with a range between 1958 and 1989. The mean year for completion of residency programs was 1981 with a range between 1963 and 1994. Thirty six percent of participating pathologists underwent fellowship training and completed this training between 1982 and 1995. Ninety-seven percent are Board-certified in pathology. Pathologists have been practicing at their current laboratory locations for between 3 months and 33 years with a mean of 9 years (S.D.=8.2 years). Pathologists have been interpreting breast pathology for 2 to 37 years with a mean of 14 years (S.D.=8.7 years). Lastly, they participated in 15 to 191 hours of continuing medical education in pathology over the past year, with a mean of 76 hours (S.D.=46 hours); this broad range is due to the mix of academic and community pathologists in the state.

Laboratory Characteristics and Specimen Preparation

The 15 pathology laboratories report submitting between 700 and 17,280 pathology cases per year (mean=5,241, S.D.=3,820). Of these, between 20 and 720 cases per year are breast tissue (mean=258, S.D.=183). Ninety-three percent of sites evaluate fine needle aspirations at an annual volume of between 10 and 224 cases (mean=74, S.D.=63), and 29% report evaluating stereotactic-guided core biopsies at an annual volume of between 5 and 104 cases (mean=70, S.D.=46).

At 64% of the labs, breast biopsies resulting from clinically detected masses or abnormal mammograms are always received in the fresh state from the operating room. In the remaining cases they are sometimes received fixed in formalin. A frozen section is performed on between 3 and 50% (mean 20% S.D.= 16%) of labs' breast biopsies. In 50% of labs, mammographic x-rays always accompany excisional and/or needle localization specimens from the operating room, and 93% of pathologists find these accompanying films useful. In 86% of laboratories, specimen radiography is performed, and of these 8% are done in pathology and 92% are done in radiology.

At 93% of pathology labs in New Hampshire, excisional and/or needle localization specimens are always inked. For 71% of labs, fresh tissue (if present in adequate quantities) is submitted for biochemical assays for estrogen receptor and progesterone receptor status in all cases of malignancy; all of these sites use out-of-state labs for ER/PR. If diagnostic tissue are limited, immunohistochemical studies for estrogen and progesterone receptivity are performed on paraffin-embedded blocks by all labs in all cases of malignancy. Twenty-one percent perform the immunohistochemical assays on-site; the remainder are sent to commercial labs. Forty-three percent of labs perform cell cycle analysis by flow cytometry in all cases of malignancy. Of these, 21% perform this on-site, with 36% performing this on fresh tissue and 57% performing it on paraffin-embedded tissue blocks.

Attitudes about Content of Breast Tissue Reports

Tables 3 and 4 outline the proportion of pathologists who selected core diagnostic criteria to be routinely included in all breast pathology reports by type of procedure, and by diagnostic outcome of the tissue sample. We are currently analyzing baseline levels of agreement for the first slide rotation and have finalized a checklist for pathologists to use in completing their breast tissue reports, which we will implement this month. The draft mini-proposal for next year's project is included in Appendix A and will focus on improving DCIS grading practices by N.H. pathologists.

Table 3 Proportion of Pathologists Who Feel These Core Diagnostic Variables Should Be Routinely Included in All Breast Pathology Reports for Benign and Malignant Disease

Core Diagnostic Variable	% Say Report in Benign Disease	% Say Report in Malignant Disease
Biopsy size	93	100
If non-invasive, state in-situ pattern	--	93
If invasive:		
Histological subtype	--	93
Grade	--	93
Presence of microcalcification	100	100
Specification of different components of FCD	86	72
Presence of hyperplasia	100	72
Presence of atypical hyperplasia	100	83
Recommendations regarding risk	35	14
Recommendations regarding F/U	24	14

Table 4 Proportion of Pathologists Who Feel These Core Diagnostic Variables Should Be Routinely Included in All Breast Pathology Reports for Non-Invasive and Invasive Carcinoma

Core Diagnostic Variable	% Say Report in Non-Invasive Carcinoma	% Say Report in Invasive Carcinoma
Biopsy size	100	100
Lesion size	90	93
Maximum diameter (cm)	83	76
Two dimensions (....x....cm)	35	41
Three dimensions (....x....x....cm)	55	62
Discrete or multifocal	100	100
Tumor histological subtype	--	100
Tumor grade (e.g.: Scarff-Bloom-Richardson, other)	--	100
Presence of associated extensive in-situ component	--	100
Estimation of % of the total tumor size	--	76
In-situ pattern	100	--
Presence of microcalcifications	97	--
Benign association	52	69
Malignant association	62	72
Presence of a mononuclear cell infiltrate	--	31
Presence of necrosis	--	83
Angiolymphatic and perineural invasion	--	100
Margin status	100	--
Involvement by infiltrating carcinoma	--	100
Involvement by in-situ carcinoma	--	97
Specification of different components of FCD	76	69
Involvement of dermal/epidermal lymphatics	--	93
Axillary LN dissections (positive vs. negative)	--	100
Correlation with previous biopsies	--	93
Involvement or not of nipple (Paget's)	93	--
Estrogen/Progesterone receptor status	72	--
Biochemical assay	62	72
Immunohistochemical evaluation	83	100
Flow cytometric cell cycle analysis	35	45
TNM classification	--	69
Recommendations regarding risk	14	--
Recommendations regarding F/U	14	10

CONCLUSIONS

We have accomplished our goals for the second year of the Project. Our greatest challenges were seeking and obtaining agreement on a standardized set of data variables and developing acceptable formats for data collection by N.H. radiologists and pathologists, mammography technologists and, most importantly, N.H. women. Our community-based steering committee was exceedingly helpful in obtaining support for the Project from their respective professional groups. We have succeeded in obtaining funding for related Projects, with the two breast pathology quality assurance studies, and are confident that the NHMN database will provide an important resource for studies on patterns of care and accuracy in mammography in the coming years.

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APPENDIX A

Pathology Quality Assurance Mini-proposal: Phase II

Draft 9/30pc

New Hampshire Breast Pathology Quality Assurance Project: A Follow-up Study

Principal Investigator: Patricia A. Carney, PhD
Co-Principal Investigator: Wendy Wells, MD

• BACKGROUND

Since the introduction of high-quality, routine mammographic screening, there has been a marked increase in the detection rate of small, non-palpable Stage I breast cancers with associated microcalcifications and the incidence of biopsied non-invasive breast carcinomas has increased fourfold [1].

Despite the importance of accuracy in pathologic assessment of breast tissue, a great deal of variability exists in intra- and inter observer agreement in certain areas of breast pathology reporting, as confirmed in the N.H. Breast Pathology Quality Assurance project. There is now a much greater emphasis on "borderline" lesions such as distinguishing between atypical ductal hyperplasia (a benign condition) and ductal carcinoma in situ (a pre-malignant condition). An error in distinguishing between these two lesions may have a profound effect on the treatment that a patient will receive as well as her long term outcomes [2, 3, 4].

Even amongst highly respected surgical pathologists with considerable experience in breast pathology, interobserver diagnostic variability has been found to be surprisingly high [3]. However, in a follow-up study, the diagnostic reproducibility of similar proliferative breast lesions was improved if previously agreed, standardized diagnostic criteria were adhered to by all participants [5].

In the past, many pathologists have attempted to describe the different types and patterns of non-invasive carcinomas of ductal origin (DCIS) [6,7,8,]. The poorly defined criteria for differentiation of these patterns have mainly concentrated on the architectural features and the presence or absence of necrosis. Recently, a classification of DCIS grading (which includes both cytological and architectural features) has been proposed which reflects how the various histological patterns correlate with the mammographic findings and predictive prognosis [9]. In this classification, the well-differentiated and poorly-differentiated patterns of DCIS have been found to correlate with low grade and high grade infiltrating tumors, respectively [10]. The poorly-differentiated patterns are associated with poor prognostic indicators (p53 and C-erb-B2 expression) and a reduced disease-free interval [11].

Unless the diagnostic reproducibility of these different DCIS grades amongst every day, practicing pathologists can be determined, the usefulness of such a grading system nationwide will remain unknown and its impact in treatment

decisions limited. As part of the first NH Breast Pathology Quality Assurance Project, we implemented a standardized reporting form, which was voluntarily accepted by participating pathologists. Though we feel this standardized reporting form will assist with an improvement in overall agreement in breast pathology reporting, special attention to specific diagnostic criteria for atypical ductal hyperplasia and ductal carcinoma in situ may further improve the diagnostic acumen in breast pathology. Our QA project for 1997 intends to not only improve the diagnostic concordance of these difficult differentials, but also assess the reproducibility of DCIS grading. This will be achieved by pursuing the following Specific Aims:

1. Assess the inter rater agreement of DCIS grade for cases selected from the New Hampshire Breast Pathology Database.
2. Develop a DCIS grade specific standardized diagnostic criteria reporting format with a core group of N.H. pathologists.
3. Assess adherence to the DCIS diagnostic criteria reporting format.
4. Reassess the inter rater agreement of DCIS cases post implementation of the DCIS standardized reporting format.

• METHODS

In the last Project we implemented a random slide selection with statewide participation by pathologists in a slide rotation and comparison study. From that study, we learned that the greatest area of discordance was between DCIS and ADH. In this new project we want to focus specifically on DCIS cases and work with a smaller group of community pathologists to assess discordance, and design a more effective standardized reporting tool for DCIS grade for later statewide dissemination.

• Phase 1

Currently, breast pathology reports are submitted to the New Hampshire Mammography Network (NHMN) in order to match pathology outcomes to diagnostic and screening mammographic encounters. During Phase 1 of the new project, we will collect DCIS cases for three months. We will then select 60 DCIS cases from the breast pathology database. We will split these cases into two groups of 30. We will request recuts of the cases from the labs that submitted them. We will recruit a core group of pathologists willing to take part in Workshops (for CME credit) with a focus on the diagnostic criteria of DCIS. Dr. Wells will assess the quality of the recut slides for assurance that the data will be comparable across recuts. We will then rotate the sets of 30 recut slides to the core group of pathologists, one group to the northern pathologists in the state and one to the southern group in the state. We will use the standardized reporting form (checklist) we developed in Year 1 of the Project to collect data for the slide review. The reporting form we are currently using does ask for *pattern types* of DCIS but does

not yet address the criteria used to *grade* DCIS - for the latter, both pattern and cytological characteristsics must be included, so we will add grade to the reporting form. After the two sets of 30 slides are rotated and assessed, we will convene two workshops for both the rater pathologists and other interested community pathologists to discuss areas of discordance, one will be held in the northern part of the state and one in the southern part. We will assess the percent of agreement on each of these cases and characterize patterns or areas that lead to the greatest areas of possible confusion and develop DCIS specific diagnostic criteria to be added to the standardized reporting format.

• Phase 2

During Phase 2, we will assess adherence to the DCIS standardized reporting format by participants of the workshops held in Phase 1. To accomplish this we will adjust the design of the breast pathology database to conform to the standardized reporting format from Phase 1. We will then enter special identifiers in the database, which will allow us to follow submissions and content of reports to the database by pathologists who participated in Phase 1 workshops. We will then design a feedback system to pathologists, which will provide back to them data they have submitted with comparisons made to projected optimal goals for data completeness. This will allow us to inform pathologists of their areas of missing data on grade, pattern type, extent of tumor, involvement of resection margins.

• Phase 3

During Phase 3, we will conduct another slide rotation of 60 cases (two groups of 30 slides) to assess whether adherence to the standardized reporting format improves agreement on DCIS cases. The cases to be rotated will be comprised of the opposite set of cases reviewed in the first set. For example if Set A were reviewed in the Northern part of the state and Set B were reviewed in the Southern part of the state during the baseline rotation period, the Sets would switch, with the Northern part of the state reviewing Set B and the Southern Set A.

• Evaluation

Data sources will include data contained in the breast pathology database, and data submitted on the breast tissue standardized reporting form (developed from Year 1 of the NH Breast Pathology QA Project) and the DCIS standardized reporting form. Descriptive statistics will be used to analyze demographic and practice characteristics of the pathologists. To achieve Specific Aim 1, we will use the kappa coefficient to assess the percent agreement (adjusted for chance) of raters across each slide in the rotation. To address Specific Aim 3 (adherence to the DCIS diagnostic criteria reporting format), we will monitor content of breast tissue reports for the specific items on the DCIS standardized reporting form and assess the proportion of those reports submitted by participants that do and do not have the DCIS specific diagnostic criteria. To address Specific Aim 4 (reassess the inter rater agreement of

DCIS cases post implementation of the DCIS standardized reporting format), we will compare the levels of agreement in the pre-DCIS standardized report form period with those in the post DCIS standardized report form period.

- Timeline

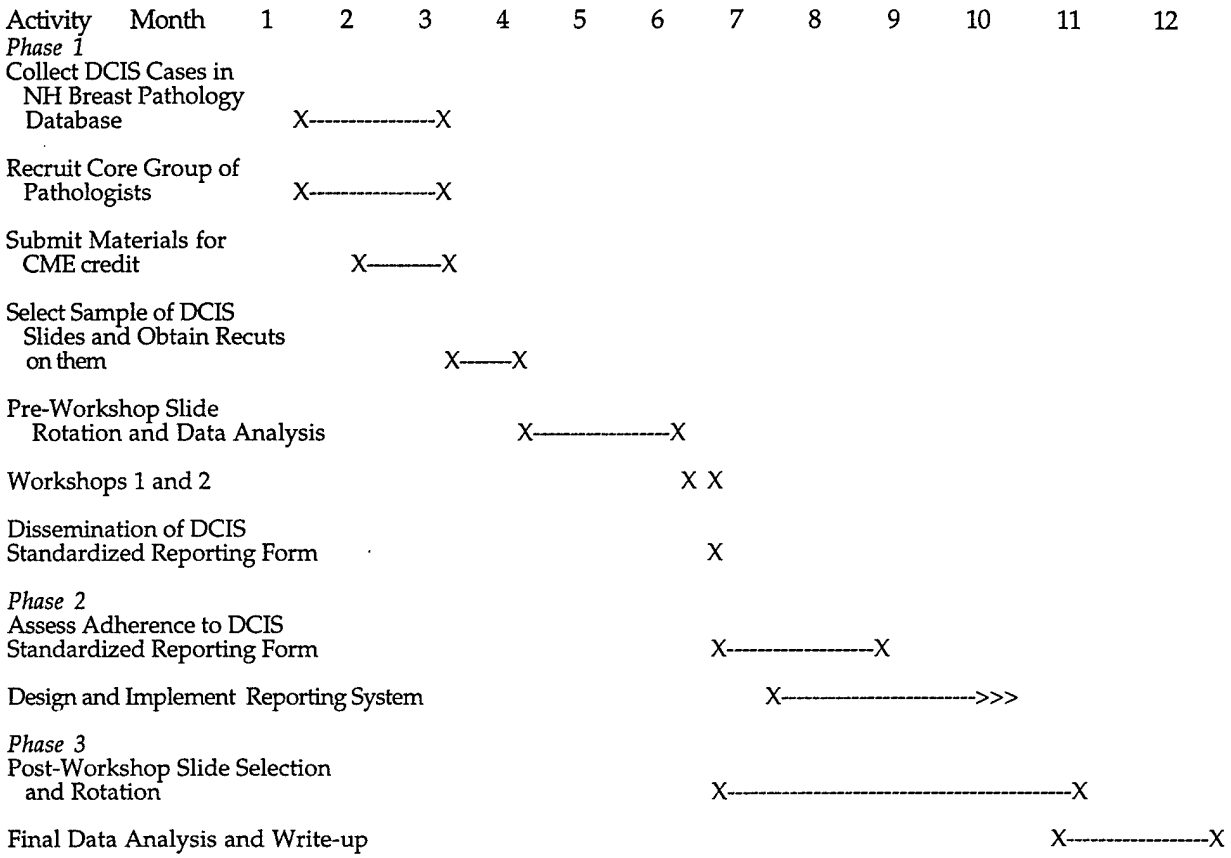

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Exhibit A

Scope of Services

The Contractor, Norris Cotton Cancer Center, shall provide services to use the established statewide breast pathology quality assurance program to improve the diagnostic acumen of N. H. pathologists in interpreting ductal carcinoma in situ. This will include establishing agreements with a core group of N.H. pathologists and N.H. pathology labs to provide breast tissue reports and selected slides for review and conducting 2 continuing medical education programs that will look specifically at DCIS cases and identify pathologic patterns that can be characterized and assessed. The project will then add DCIS specific diagnostic criterion to the standardized reporting form developed last year (1996), monitor adherence to the DCIS standardized Reporting Form and conduct a second slide rotation to assess the level of discordance post workshop and post implementation of the special form.

All services shall be provided in cooperation with, and subject to the approval of, the New Hampshire Department of Health and Human Services, Division of Public Health Services, Office of Community and Family Health (here within referred to as Division) in time frames to be agreed upon with the Division. The project will be carried out in three phases: recruitment and baseline assessment and implementation, DCIS quality assurance adherence phase and post-quality assurance assessment phase.

1. In Phase 1 the Contractor will continue the established administrative infrastructure for the Project and conduct baseline assessment of DCIS cases in N.H. Services to be provided by the Contractor in Phase I shall include:

1.1 Continue with the established administrative unit as part of the New Hampshire Mammography Network to oversee and administer the breast pathology quality assurance project, which will be conducted in an estimated 12-15 laboratories throughout the state.

1.2 Continue with the established system with participating laboratories and with the pathologists who read breast tissue for reports to be sent to the administrative unit for processing.

1.3 Evaluate for completeness the information provided, using the standardized reporting forms and data collection instruments developed during the last project year (1996).

1.4 Review approximately 300 cases in this phase of the study.

1.5 Recruit a core group of between 7-10 N.H. pathologists to take part in the slide rotation and subsequent CME workshops.

1.6 Review all DCIS cases submitted to the breast pathology database during the initial three month period. A total of 60 (two groups of 30) cases will be selected. If necessary, we will select cases from 1996 study to achieve the acceptable number of cases.

1.7 Request recuts from selected labs for slide rotation (for baseline data collection) and check the recuts for comparability.

1.8 Record the slides from each laboratory, cover any identifying slide labels and send all slides to each core pathologist for independent evaluation using a universal data reporting form (Attachment A). All slides will be assembled in batches and sent around in an unidentified manner.

1.9 Analyze baseline data from Pre-workshop slide rotation.

1.91 Hold two continuing medical education workshops, one in the northern part of the state and one in the southern part of the state with core pathologists and all other invited pathologists in N.H. to discuss discordant cases from baseline data and develop specific diagnostic criterion for DCIS interpretation.

2. In Phase 2 the Contractor will identify the degree of adherence to DCIS specific standardized reporting form in pathology practices for cases of DCIS. Services to be provided by the Contractor in Phase 2 shall include:

2.1 Adaptation of the database design to track reports submitted by those pathologists who participated in the workshops to monitor adherence to the DCIS Standardized reporting form.

2.2 Design a feedback system to pathologists, which will feedback data they have submitted compared to projected optimal goals. This will allow us to inform pathologists of their areas of missing data.

In Phase 3 the Contractor will assess the impact of the workshops and implementation of the DCIS standardized reporting form on pathology practices. Services to be provided by the Contractor in Phase 3 shall include:

3.1 Conduct a second slide selection and rotation for post-intervention assessment.

3.2 Provide CME credits for participants in any and all aspects of the project.

3.3 Utilize methods for slide selection and numbering, assembling of batches and distribution identical to those used in Phase 2. The same universal data reporting form developed in Phase 1 will be used for data collection purposes.

3.4 Conduct a review of all data for completeness and enter all data into a database for evaluation. The Kappa Coefficient (percent agreement adjusted for chance) will be used to evaluate the degree of concordance between different observers for each slide read.

3.5 Conduct assessment of the quality assurance program by comparing Phase 1 Kappas with those collected during Phase 3.

4. The Contractor shall provide the following Administrative services:

4.1 Meet with the Division staff relative to project progress on a regular basis in a time frame to be agreed upon with the Division.

4.2 Provide to the Division written progress reports, on a quarterly basis, in an agreed upon format.

4.3 Submit to the Division all project data, materials, manuals, reports, within 3 months of the contract end date.

4.4 Credit the Division on all written project materials and published articles and reports. The following wording shall also be used for the same purposes: "This project is funded in part by the Centers for Disease Control and Prevention Breast and Cervical Cancer Early Detection Program through funding awarded to the New Hampshire Department of Health and Human Services, Division of Pubic Health Services, Office of Family and Community Health."

APPENDIX B

NHMN General Information Form Completed by Participants

A 0 0 9 1 5 4 2

MAMMOGRAPHY FACILITY MUST COMPLETE

Patient's Medical Record #: _____

Patient's Date of Birth: _____ - _____ - _____
MM DD YY

NH Mammography Network General Information

Patient's Name: _____
Last First Middle

Address: _____

_____

_____

Zip code: _ _ _ _ _

Today's Date: _ _ - _ _ - _ _
month day year

PLEASE CLEARLY PRINT ALL INFORMATION

Please read the information below before you fill out the attached survey.

Information about the New Hampshire Mammography Network Project

Your mammography center is working with the Norris Cotton Cancer Center and Dartmouth Medical School to develop a registry (a computer database) of mammograms that will help us understand breast problems, including breast cancer. The registry is called the New Hampshire Mammography Network. It collects information on all mammograms performed in New Hampshire, including the procedure you are having today. It is used to help your facility comply with Federal regulations that all mammography facilities must meet.

We are asking you to help us expand the usefulness of this registry by giving us additional information on the attached survey. The survey is for research purposes only. It is not part of your routine procedure for mammography. **Your participation is strictly voluntary. Whether you participate or not, your decision will have no effect on your medical care.**

The information you give us on the attached survey will be entered into our New Hampshire Mammography Network, along with your mammography results. However, if you are a resident of Vermont, your information will be transferred to a similar registry in Vermont. Neither our registry nor the Vermont registry will release any information that allows you to be identified. Although data collected may be shared with other investigators, your name and other identifying information will not be revealed.

If, after your mammogram, you have additional diagnostic studies or treatment related to breast problems, we may need to review your medical records to help us fully understand your mammography results. Rarely, we also may wish to contact a patient or her doctor directly to ask for more information. This may occur once or twice for every 200 mammograms we receive.

Please Note: If there are any questions on the survey that you do not wish to answer, simply leave them blank. If you do not wish to participate in this research study, please hand all the forms back to the receptionist or mammography technologist.

If you have any questions regarding the NH Mammography Network Project, please call the Norris Cotton Cancer Center at 603-650-4135. Ask to speak with Karen Burgess or Patricia Carney.

Permission: We ask your permission to use your data in our project, and, if needed, to review your record or to contact you or your doctor for additional information. Please sign here to indicate that you are willing to participate fully in these activities.

Signature:_____

Thank you for your cooperation!

final 4/96

49344

NH Mammography Network
General Information

A 0 0 9 1 5 4 2

Instructions:

Please complete this questionnaire using a No.2 pencil or blue or black pen.
All letters and numbers must be written in capital block style **without touching the sides.**

0	1	2	3	4	A	B	C	D	E

Please shade circles like this: ●

1. MAMMOGRAM HISTORY

Are you having a mammogram today because: (Choose one)

- ○ **Both you and your health care provider** are concerned about a breast change (lump, pain, etc)?
- ○ **You** are concerned about a breast change?
- ○ **Your health care provider** is concerned about a breast change?
- ○ **Routine Screening Exam** - no breast changes but I or my health care provider wanted a routine mammogram?

When was your last mammogram? (Choose one)

- ○ Within the last 12 months
- ○ 1 to 2 years ago
- ○ 3 to 4 years ago
- ○ 5 or more years ago
- ○ Never had a mammogram before

When did a health care provider last examine your breasts? (Choose one)

- ○ Within the last 12 months
- ○ 1 to 2 years ago
- ○ 3 to 4 years ago
- ○ 5 or more years ago
- ○ Never

2. PERSONAL HISTORY

What is your date of birth?

		/			/				
M	M		D	D		Y	Y	Y	Y

What is your social security number?

			-			-				

(To Avoid Duplication of Records)

What is your racial or ethnic background? (optional) (Choose one)

- ○ White/Caucasian
- ○ Black/African-American
- ○ Native American (American Indian)
- ○ Hispanic/Latina
- ○ Asian/Pacific Islander
- ○ Other (please specify) _____

What is your maiden name (last name only)**?**

Where were you born?

○ USA ○ Other _____

If born in USA, in which state were you born?

State (e.g. NH, VT, MA, ME, etc.)

What is your current marital status? (Choose one)

- ○ Single ○ Divorced
- ○ Married ○ Widowed
- ○ Separated

2. PERSONAL HISTORY (Contd.)

What is the highest level of education you have completed? (Choose one)

- ○ 8th grade or less
- ○ Some high school
- ○ High school graduate
- ○ Associate's degree or some college/tech school
- ○ College graduate (4 yrs)
- ○ Postgraduate

What is your health insurance coverage?
(Please shade all that apply)

- ○ None
- ○ Private Insurance (Blue Cross, AETNA etc)
- ○ Medicare
- ○ Medicaid
- ○ HMO or PPO (Preferred Provider Organization)
- ○ CHAMPUS, CHAMPVA or similar
- ○ Other: _____

What is your current height?
(to the nearest inch)

Feet Inches

e.g. 5 ft 6½ ins. = 5 0 7

What is your current weight?

Pounds

e.g. 98 lbs. = 0 9 8

What did you usually weigh (when not pregnant) when you were between 18 and 20 years old?

Pounds

3. HEALTH HISTORY

How old were you when you had your first menstrual period? (Choose one)

- ○ Under 11
- ○ 11
- ○ 12
- ○ 13
- ○ 14
- ○ 15 or older

Have your Periods stopped permanently?

○ No ○ Yes

If Yes, did your Periods stop due to:
(Choose one)

- ○ Natural Menopause
- ○ Surgery (Hysterectomy)
- ○ Radiation or Chemotherapy
- ○ Other: _____

Have you ever had an ovary removed?
(Choose one)

- ○ No Ovary Removed
- ○ Yes, One Ovary Removed
- ○ Yes, Both Ovaries
- ○ Yes, but Don't Know if One or Both
- ○ Don't know

How old were you at the time of your first full term pregnancy? (by full term we mean a pregnancy lasting 6 months or more)
(skip if not applicable)

Age

How many times have you been pregnant, if ever? (can be zero)

Number of Full Term Pregnancies + Number of Early Pregnancy Losses = Total Pregnancies

Thank You!

APPENDIX C

NHMN Patient Intake Form and Radiologist Form (see reverse side of Patient Intake Form - top copy).

48440

Patient Intake (Tech.) Form

B0095518

DATA LINKS

Name: _____ (Last) _____ (First) _____ (Middle Initial)

Date of Exam: ____ - ____ - ____ (mm dd yy)

Social Security #: _____ - _____ - _____

Zip Code: _____

Date of Birth: ____ - ____ - ____ (mm dd yy)

Tech Initials: _____

Referring Physician's Name: _____

Referring Physician's Town: _____

Medical Record #: _____

Did the Patient read & sign the NHMN Survey Consent Form?

○ No ○ Yes

Has the Patient had a previous mammogram?

○ No ○ Yes

Date of Last Mammogram: ☐☐ / ☐☐ / ☐☐ (m m / d d / y y)

Location/State: _____

Does the Patient have any breast concerns?

○ No ○ Yes

If Yes, who **first** became concerned? (choose ONE)

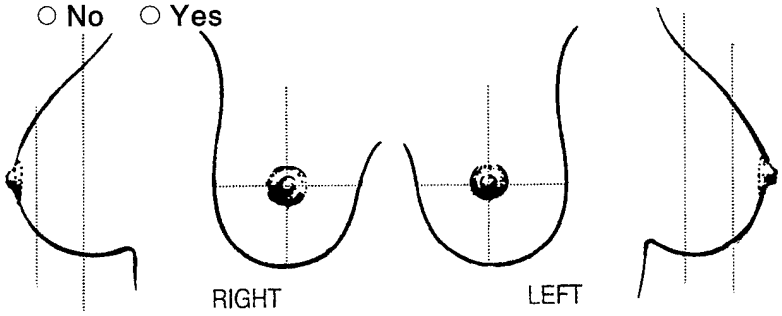
○ Self ○ Partner ○ Physician/Nurse

How long has there been concern? (e.g enter 01 for 1 month or less) ☐☐ Months

Type of concern:	L	R	B	
Lump	○	○	○	
Nipple Discharge	○	○	○	
Skin Changes	○	○	○	
Other (please specify)	○	○	○	_____

Has the Patient had any past breast procedures?

○ No ○ Yes



Type of procedure:	L	R	B	Date(s) Completed
Breast Reduction	○	○	○	_____
Breast Implants	○	○	○	_____
Needle Biopsy	○	○	○	_____
Surgical Biopsy	○	○	○	_____
Lumpectomy	○	○	○	_____
Mastectomy	○	○	○	_____
Breast Reconstruction	○	○	○	_____
Radiation Therapy	○	○	○	_____

Comments: _____

Has the Patient ever had breast cancer?

○ No ○ Yes If yes, age at diagnosis? ☐☐ Age

Which breast? L ○ R ○ B ○

How many **sisters/daughters** with breast cancer? ☐

Is there a family history of breast cancer?

○ No ○ Yes ○ Unknown (e.g. adopted)

If yes, please specify: ○ Mother ○ Sister(s) ○ Other ○ Daughter(s) ☐

Have the Patient's periods stopped permanently?

○ No ○ Yes ○ Not Sure

If yes or not sure, is she currently taking hormone replacement therapy? ○ No ○ Yes

If yes, how long? _____

48440

New Hampshire Mammography Network
Radiologist Interpretation Form

B 0 0 9 5 5 1 8

Please be sure that the patient's name and data links are completed on the other side!

Please shade circles like this: ●

1. TYPE OF EXAM: (Choose ONE per breast)

B ○ L ○ R ○ **Asymptomatic** (Screening Mammogram)

	L	R	B
Screening & Additional Views (Single Aggregate Report) . .	○	○	○
Diagnostic Mammogram (for Clinical Indication)	○	○	○
Follow-Up at Short Interval (to Evaluate Stability)	○	○	○
Additional Views to Supplement Recent Mammogram (Reported Separately from Screen)	○	○	○

○ No ○ Yes **2.** Were **COMPARISON MAMMOGRAMS** used for interpretation?

○ No ○ Yes **3.** Was **BREAST ULTRASOUND** used to complete the assessment?

4. BREAST COMPOSITION: (Choose ONE and code by densest breast)

○ Fat ○ Scattered ○ Heterogenously Dense ○ Extremely Dense

5. ASSESSMENT STATUS: (Choose ONE per breast)

B ○ L ○ R ○ **Negative (ACR 1)**

	L	R	B
(ACR 0) Assessment Incomplete	○	○	○
(ACR 2) Benign Finding-Negative	○	○	○
(ACR 3) Probably Benign Finding	○	○	○
(ACR 4) Suspicious Abnormality	○	○	○
(ACR 5) Highly Suggestive of Malignancy	○	○	○

6. RECOMMENDATION: (Choose all that apply)

B ○ L ○ R ○ **Routine Screening Mammogram**

	L	R	B
Follow-up Mammogram at Short Interval . . .	○	○	○
Additional Views to Supplement Current Exam	○	○	○
Breast Ultrasound	○	○	○
Clinical Breast Exam	○	○	○
Surgical Consult	○	○	○
Biopsy (including FNA)	○	○	○

in ☐☐ months

Additional Comments (optional): _____

Rad. Initials ☐☐☐

4/18/96

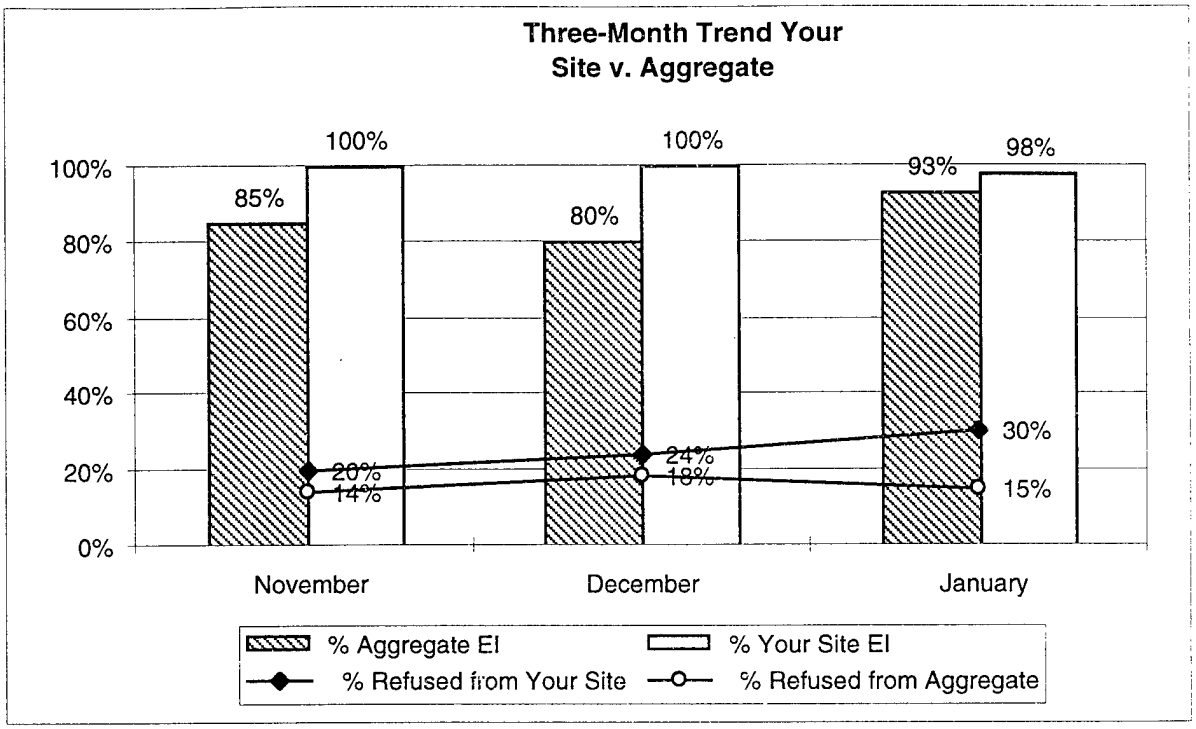
APPENDIX D

Sample Status Report Form (process measures)

Hypothetical Data

New Hampshire Mammography Network
Norris Cotton Cancer Center • One Medical Center Drive, HB 7920, Lebanon, New Hampshire 03756-0001
Phone: 603-650-4135 or 4131 Fax: 603-650-4152

STATUS REPORT



Three-Month Trend Your Site v. Aggregate

Total participants registered in the NHMN for this three-month period is 2592. Total participants registered from YOUR SITE for this three month period is 384 This chart indicates a three-month trend in the completeness of the radiologist forms received from your site (lightly shaded bar) compared to the aggregate (striped shaded bar). Also, specific for your site, the chart indicates the percentage of those who declined to participate (connected diamonds).

% Aggregate EI- This represents the essential information present on the radiologist form (indication for the exam, density, assessment, and recommendations) for all site currently participating.

% Your Site EI-This represents the essential information present on the radiologist from (indication for the exam, density, assessment, and recommendations) for your site.

% Refusals from Aggregate-This represents the % of patients forms where the consent was not signed, indicating they refused to participate, from all sites currently participating.

% Refusals from your site- This represents the % of patients forms where the consent was not signed, indicating they refused to participate, from your site.

Findings/Recommendations

Of the total participants registered from your site within this three-month period (n=384) we have recorded;

Probably Benign	8
Suspicious Abnormality	3
Highly Suggestive	1
Biopsy Recommendations	1
Diagnostic Mammography	8
Breast Ultrasound	5
Clinical Exam	0

Thank you for your continued effort to ensure the accuracy and completeness of the data. Keith Hamilton Participant Registration Coordinator 650-4148

Hypothetical Data

New Hampshire Mammography Network
Norris Cotton Cancer Center • One Medical Center Drive, HB 7929 Lebanon, New Hampshire 03756
Phone: 603-650-4135 or 4131 Fax: 603 650-4132

% Findings and Recommendations by Radiologist

	Rad. "1"	Rad. "2"
Prob. Benign	3.1%	0.0%
Susp. Abnorm.	0%	0.0%
Highly Suggest.	0.0%	0.0%
Biopsy Rec.	0.0%	0.0%
Diagnostic Mam.	1.9%	0.0%
Breast Ultraso.	1.9%	0.0%
Clinical Exam	0.0%	0.0%
		0.0%

	Rad. "3"	Rad "888"
Prob. Benign	4.0%	0.0%
Susp. Abnorm.	4.0%	0.0%
Highly Suggest.	>.09%	0.0%
Biopsy Rec.	2.4%	0.0%
Diagnostic Mam.	4.0%	0.0%
Breast Ultraso.	1.6%	0.0%
Clinical Exam	0.0%	0.0%

APPENDIX E

Pathology Abstraction Form

NH Mammography Network -- Pathology Form

Patient ID | Med Rec # | Pathologist Code
NHMN ID | DOB / / | Lab Code
Sex | Case # | Consultation / /
Date of Procedure / / | Specimen
Phys Last | Phys First
HISTORY: Previous Bx? | Previous Case #

CURRENT SPECIMEN:
- Mastectomy
- Axillary
- Excisional Bx
- Needle Loc
- Core Bx

UNSATISFACTORY:
- Unsat41
- Unsat42
- Unsat43
- Unsat44
- Unsat441
- Unsat442
- Unsat443

FINE NEEDLE ASPIRATION:
FNA | FNA Diagnosis

BENIGN:
- Normal Breast Tissue
- Fibroadenoma
- Papilloma - Single
- Papilloma - Multiple
- Fibrocystic Changes
- Ductal Hyperplasia
- Lobular Hyperplasia
- Atypical Ductal Hyp
- Atypical Lobular Hyp
- Radial Scar
- Benign Microcalcifications
- Other Lesion

MALIGNANT:

INVASIVE CARCINOMA:
- Infiltrating Ductal NOS
  - Medullary
  - Tubular
  - Muc/Colloid
  - Other Ductal
- Infiltrating Lobular
  - Other Lobular
- Other Malignant

NON-INVASIVE:
- Lobular CIS
- Ductal CIS
  - Comedo
  - Cribriform
  - Solid
  - Micropapillary

Microinvasive

GRADE:

Size Infiltrating Lesion
Size In Situ Lesion

Angiolymphatic Invasion

Paget's Disease

Margins of Excision Involved? | By In Situ | By Infilt.

Lymph Nodes | # Positive | # Negative

Microcalcifications | In Situ | Infiltrating

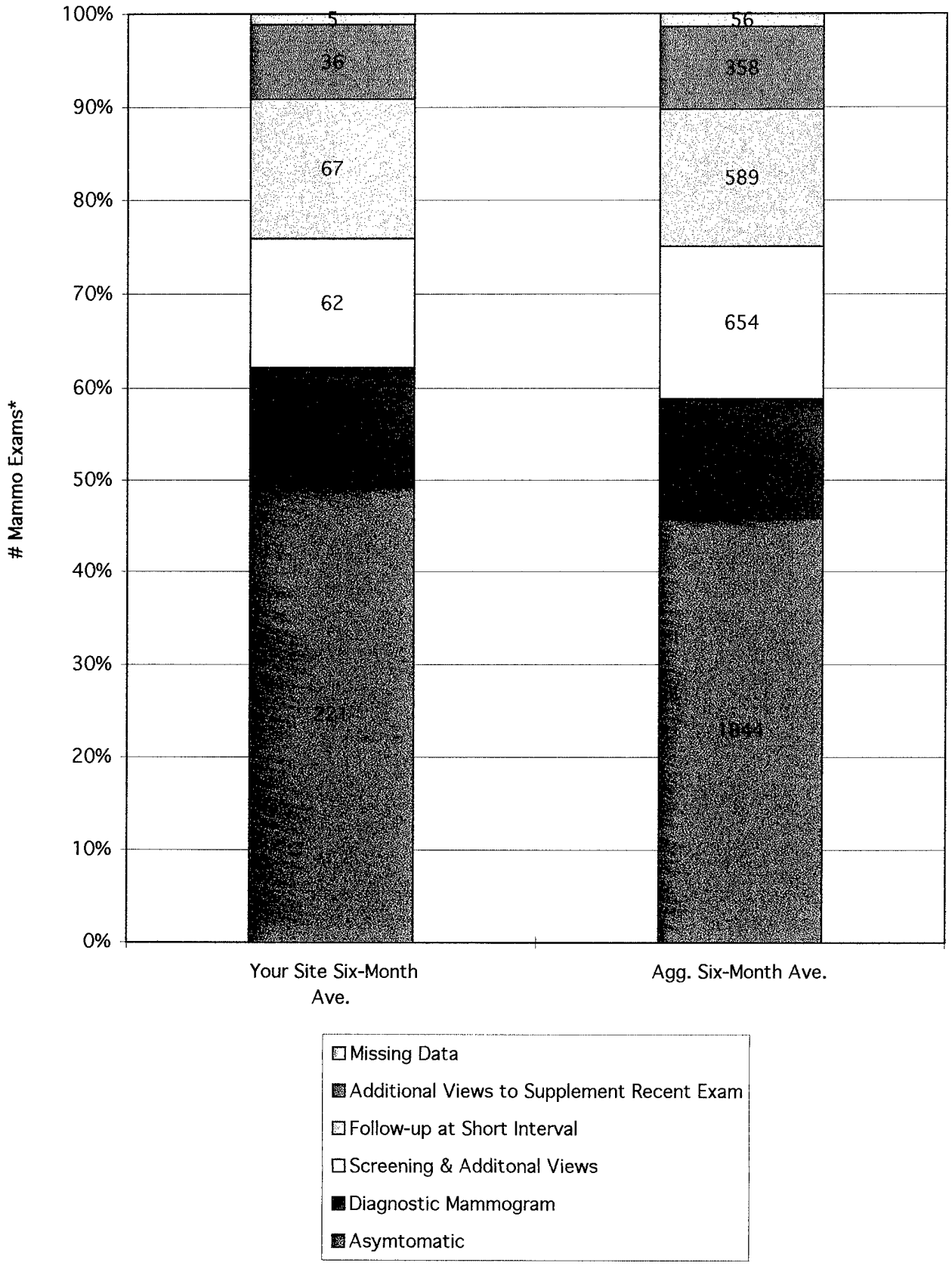
ER
PR

DNA Index
S Phase

APPENDIX F

Sample Feedback Charts (outcome measures)

Six-Month Average Volume By Type of Exam
Site_____ v. Agg.

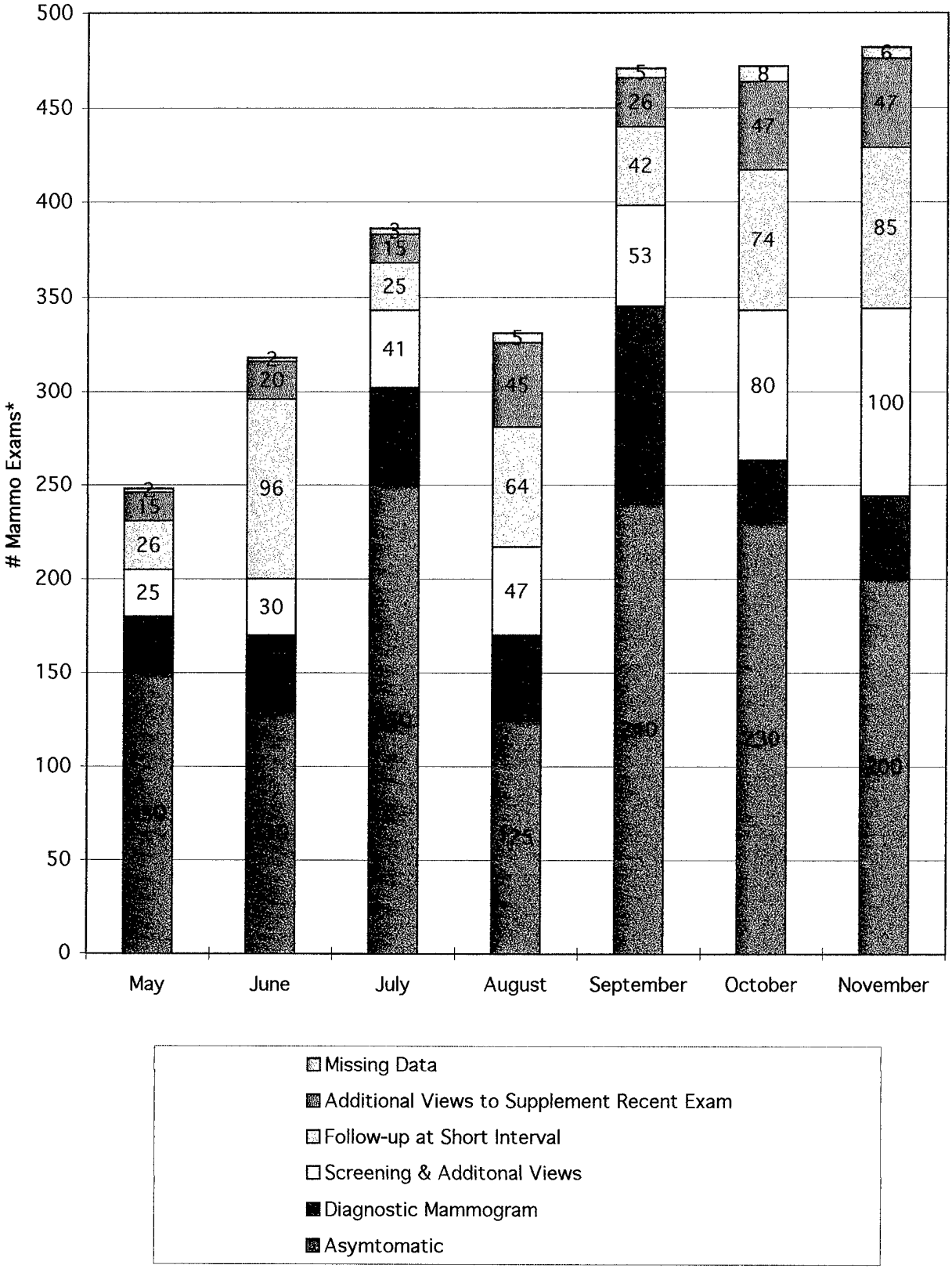


Hypothetical Data
Review for Content Only

*code by most involved breast

KH10/28/96

Monthly Volume by Type of Exam
Site_____



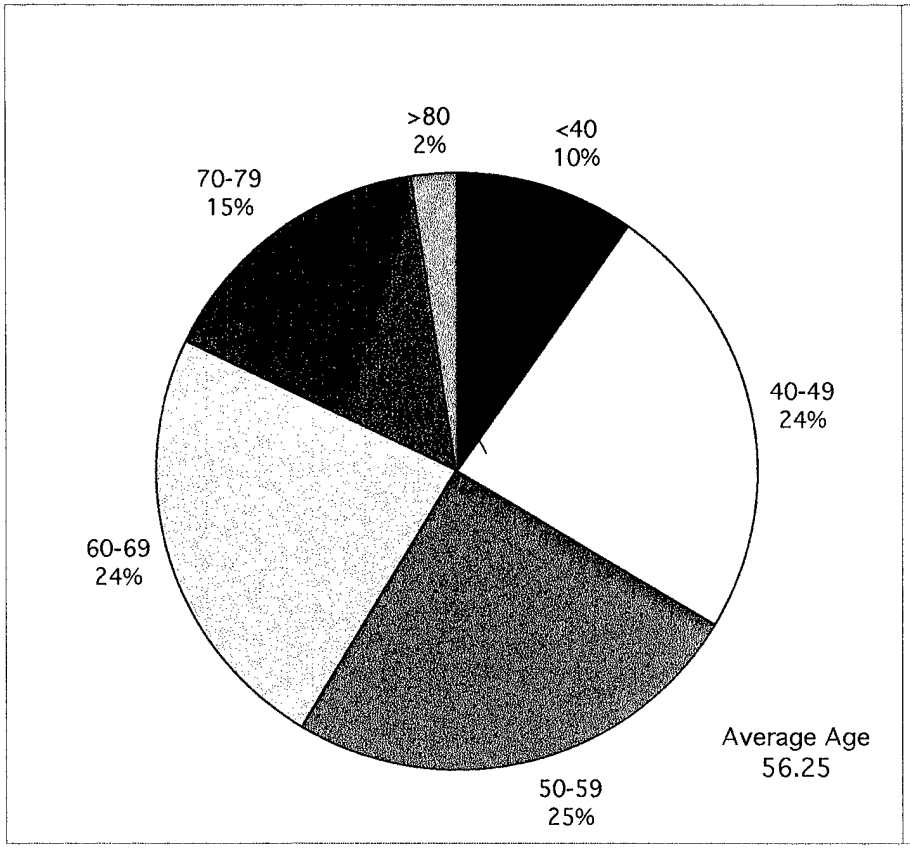
Hypothetical Data
Review for Content Only

*code by most involved breast

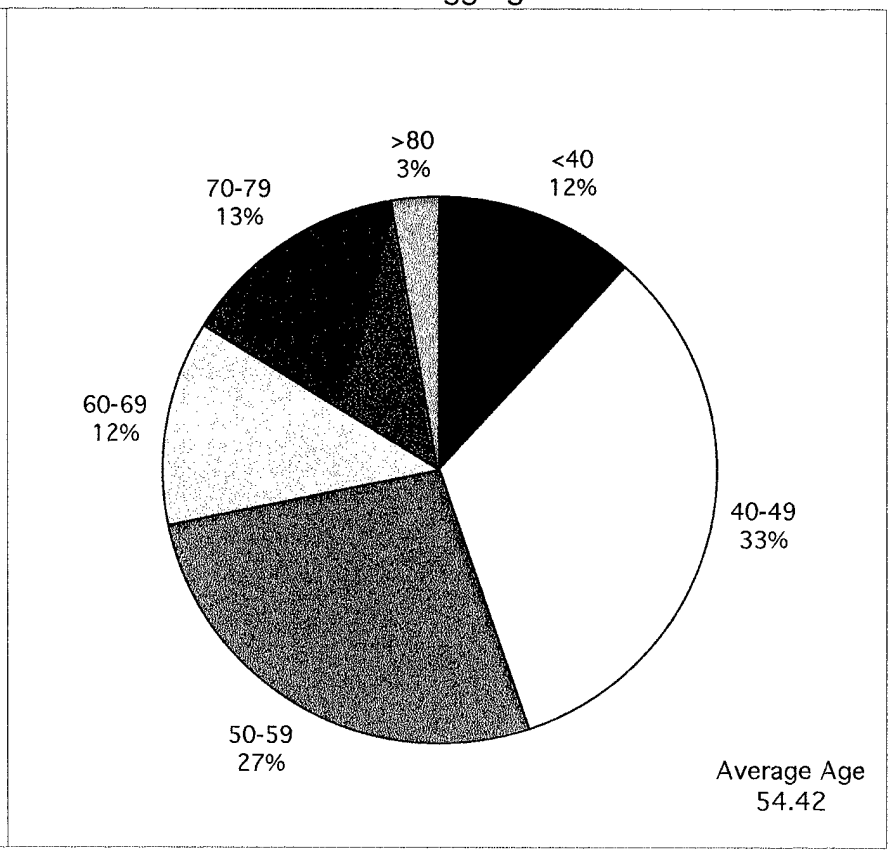
KH10/28/96

Six-Month Age Distribution

Site _____



State Aggregate



Hypothetical Data
Review for Content Only

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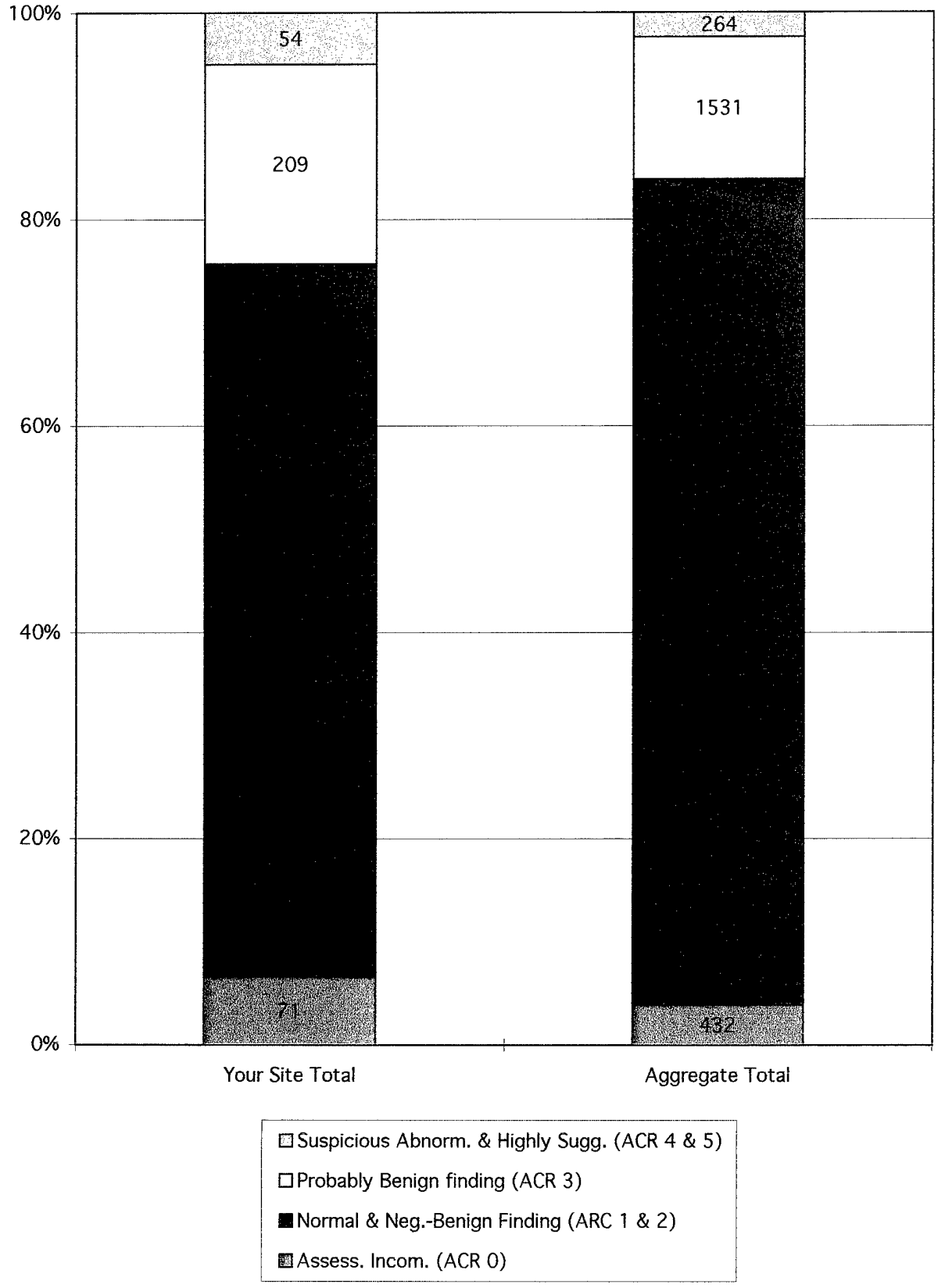
ACR Assessment Status-Site____ v. Aggregate
% and Raw Numbers



Hypothetical Data
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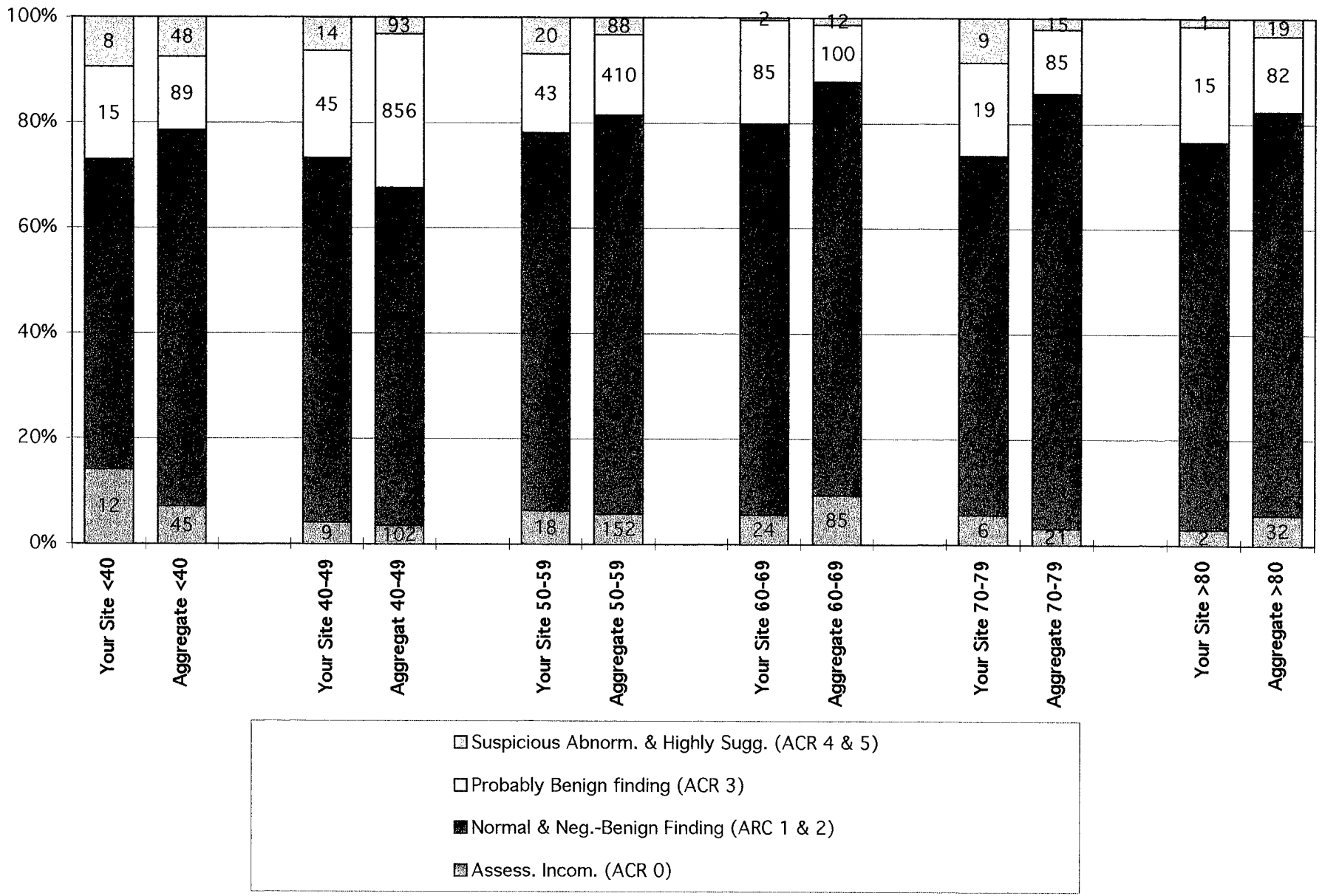
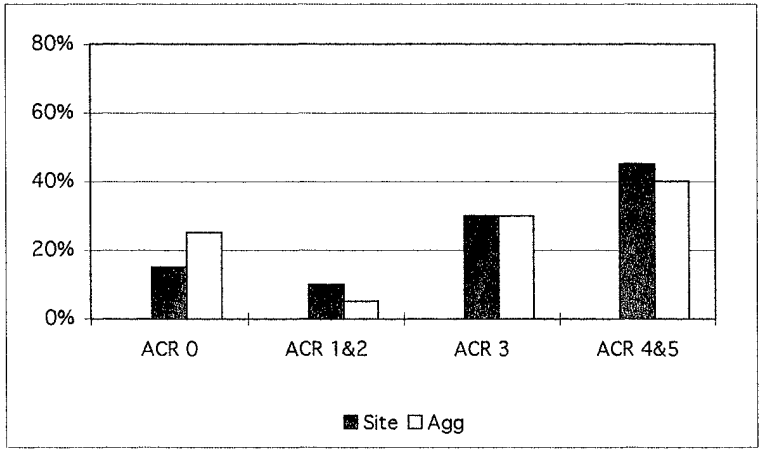
Assessment Status by Patient Age



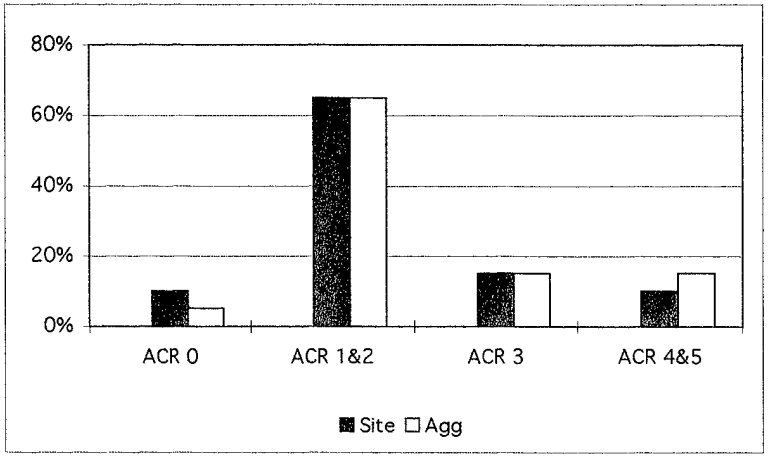
Hypothetical Data
Review for Content Only

KH10/28/96

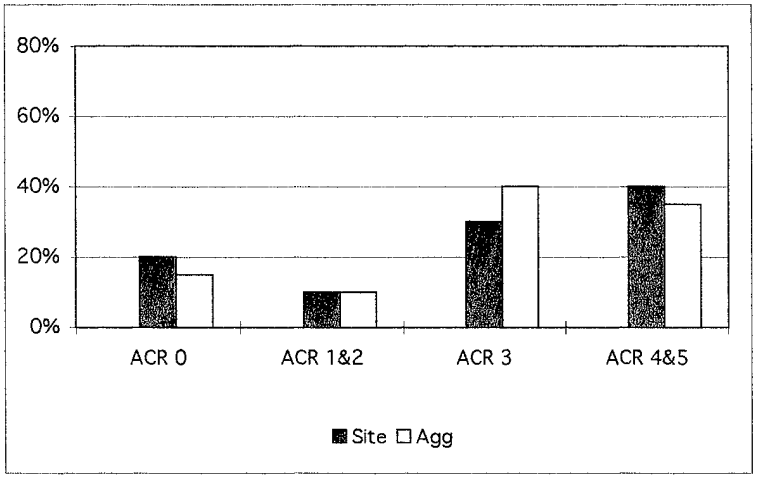
Assessment Frequency by Pathology for Site/State Aggregate



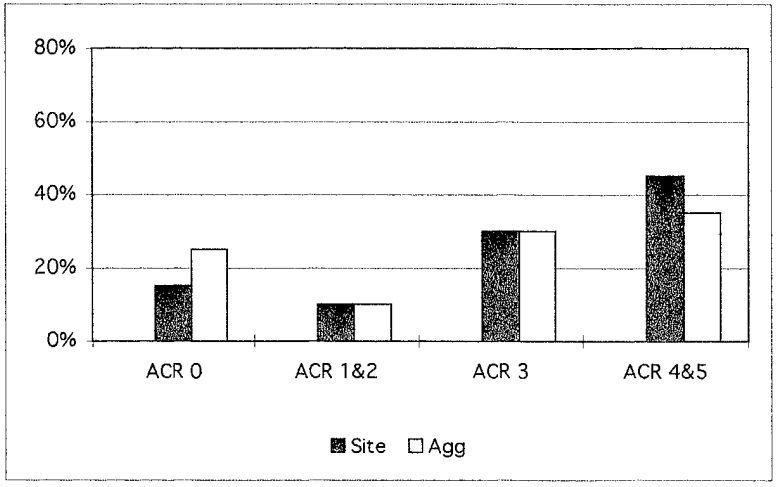
No Patholoigy (to date)



Benign



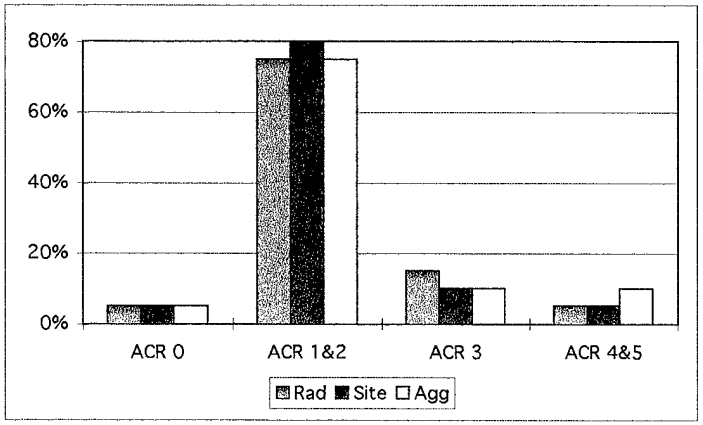
Atypical



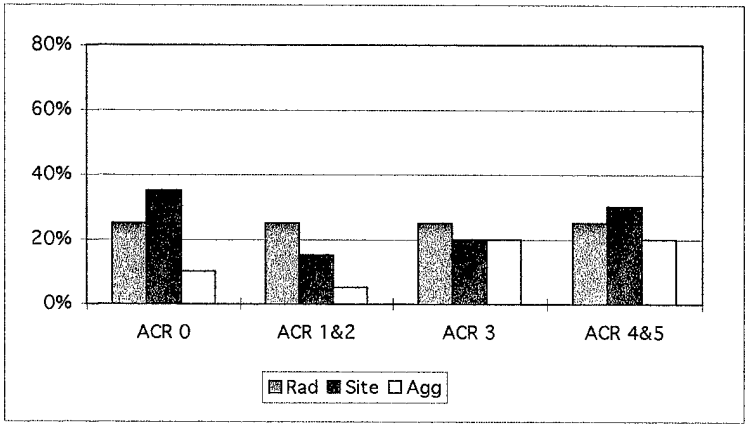
Malignant

	No Pathology (to date)				Benign				Atypical				Malignant			
	Your Site		State Agg.		Site Code		State Agg.		Your Site		State Agg.		Your Site		State Agg.	
	%	#	%	#	%	#	%	#	%	#	%	#	%	#	%	#
ACR 0	10%	50	5%	80	15%	6	25%	20	20%	8	15%	12	15%	3	25%	25
ACR 1 & 2	65%	325	65%	1040	10%	4	5%	4	10%	4	10%	8	10%	1	10%	10
ACR 3	15%	75	15%	240	30%	12	30%	24	30%	12	40%	30	30%	6	30%	30
ACR 4 & 5	10%	50	15%	240	45%	19	40%	35	40%	16	35%	26	45%	8	35%	35
Total	100%	500	100%	1600	100%	41	100%	83	100%	40	100%	76	100%	18	100%	100

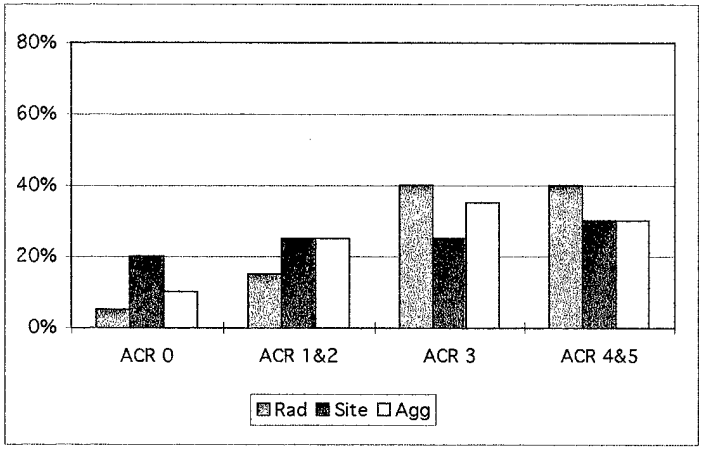
Assessment Frequency by Pathology for Rad/Site/State Aggregate



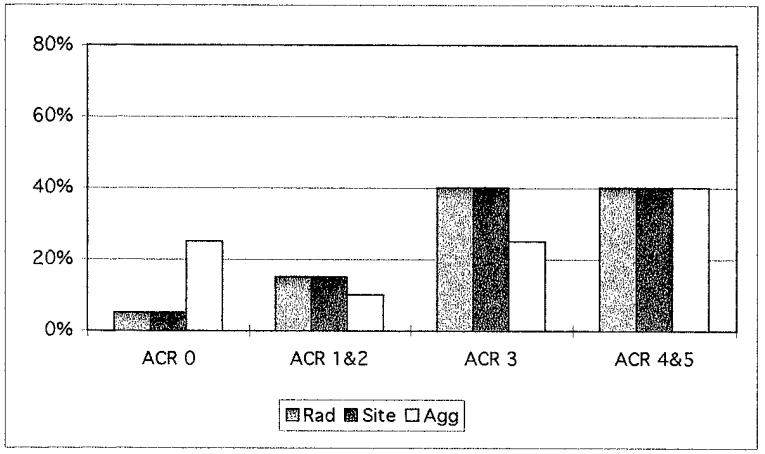
No Patholology (to date)



Benign



Atypical



Malignant

	No Pathology (to date)						Benign						Atypical						Malignant					
	Radiologist		Your Site		State Agg.		Radiologist		Your Site		State Agg.		Radiologist		Your Site		State Agg.		Radiologist		Your Site		State Agg.	
	%	#	%	#	%	#	%	#	%	#	%	#	%	#	%	#	%	#	%	#	%	#	%	#
ACR 0	5%	5	5%	10	5%	100	25%	2	35%	7	10%	8	5%	1	20%	8	10%	15	5%	1	5%	2	25%	25
ACR 1 & 2	75%	75	80%	160	75%	1600	25%	2	15%	3	50%	40	15%	3	25%	10	25%	37	15%	3	15%	6	10%	10
ACR 3	15%	15	10%	20	10%	200	25%	2	20%	4	20%	16	40%	8	25%	10	35%	43	40%	8	40%	16	25%	25
ACR 4 & 5	5%	5	5%	10	10%	100	25%	2	30%	6	20%	16	40%	8	30%	12	30%	35	40%	8	40%	16	40%	40
Total	100%	100	100%	200	100%	2000	100%	8	100%	20	100%	80	100%	20	100%	40	100%	130	100%	20	100%	40	100%	100

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Pathology Results

Site Name

Mammography Results	Malignant (+)	Benign (-)	No Pathology
ACR Assessment 0,3,4,5 (+)			
ACR Assessment 1,2 (-)			

State Aggregate

Mammography Results	Malignant (+)	Benign (-)	No Pathology
ACR Assessment 0,3,4,5 (+)			
ACR Assessment 1,2 (-)			

Mammography Results	Malignant (+)	Benign (-)	No Pathology
ACR Assessment 0,4,5 (+)			
ACR Assessment 1,2,3 (-)			

Mammography Results	Malignant (+)	Benign (-)	No Pathology
ACR Assessment 0,4,5 (+)			
ACR Assessment 1,2,3 (-)			

	Site	State
Sens.*		
Spec.*		
PPV*		
NPV*		

*Assumes data that lacks pathology is benign.

Patient Results and Outcomes

Biopsy Results

Name	Date of Mammo.	Bx. Results	Date of Biopsy	ACR Code
Belding, Julie	4/5/95	Benign	6/4/95	ACR 0
Fairweather, Sally	5/2/95	Atypical	6/8/95	ACR 3
Galluzo, Jean	6/4/95	Inv.	7/22/95	ACR 3
Hall, Terri	11/15/95	Atypical	12/1/95	ACR 4
Meehan, Pat	12/5/95	DCIS	1/5/96	ACR 3
Webber, Susan	9/5/95	Benign	10/2/95	ACR 1

Biopsy Recommended

Name	Date of Mammo.	Bx. Results	Date of Biopsy	ACR Code
Allen, Carol	4/5/96	Pending	Pending	ACR 5
Davis, Mary	1/23/96	Atypical	3/8/96	ACR 4
Gray, Mary	8/9/95	Benign	11/30/95	ACR 4
Hamilton, Keith	10/4/95	Pending	Pending	ACR 5
Meadows, Linda	11/8/95	DCIS	1/26/96	ACR 4
Roberts, Dawn	2/16/96	Iva. Ca.	4/8/96	ACR 5

Patient Results and Outcomes

Short Interval Follow-up Recommended

Name	Date of Mammo	F/U Interval And Projected Date for Return		1st F/U Date	1st F/U Assess.	1st F/U Rec.	Path. Outcome
Bryan, Paula	1/5/96	12	1/5/97	Pending	Pending	Pending	Pending
Fries, Sue	2/24/96	9	11/24/96	Pending	Pending	Pending	Pending
Koop, Margo	1/15/96	6	7/15/96	5/29/96	ACR 3	Bx.	7/8/96 (-)
McPeet, Denise	4/26/96	6	10/26/96	9/8/96	ACR 2	12 Month f/u	Pending
Pollard, Gayle	3/30/96	6	9/30/96	10/5/96	ACR 4	Bx.	10/25/96 (+)
Ryan, Anne	7/12/96	6	1/12/97	Pending	Pending	Pending	Pending
Stone, Jo	6/16/96	6	12/16/96	Pending	Pending	Pending	Pending
Trice, Fred	5/8/96	9	2/8/97	10/28/96	ACR 1	12 Month f/u	Pending
Woo, Judy	8/20/96	9	4/20/97	11/4/96	Pending	Pending	Pending

APPENDIX G

Recent Publication and Related Commentary about the NHMN

The New Hampshire Mammography Network: The Development and Design of a Population-Based Registry

Patricia A. Carney[1]
Steven P. Poplack[2]
Wendy A. Wells[3]
Benjamin Littenberg[4]

OBJECTIVE. Some authors have proposed a national mammography registry to improve and monitor breast diagnostic practices. However, issues such as confidentiality, accuracy, and direct and indirect costs are practical barriers to implementing such a registry. This paper describes the development and design of a population-based mammography registry in New Hampshire. The project's objectives are to assess the accuracy of mammography by comparing interpretive results with pathology and tumor-registry reports and to improve mammographic performance by reporting findings to facilities, radiologists, and pathologists statewide.

MATERIALS AND METHODS. We recruited radiologists and pathologists through professional associations and facilities through site visits. Data used to develop and design the registry were collected during site visits, using structured face-to-face interview methods. Only one site refused to provide site-specific information.

RESULTS. Facilities in New Hampshire estimated the annual mammographic volume to be approximately 148,000. We have noted a great deal of variability in mammography practices. Their principal methods for determining screening versus diagnostic mammograms were by patient self-reports (44% of practices), referring physicians' reports (38%), and radiologists' reports (18%). Although 71% of practices have computers, only 16% have radiology information systems or hospital information systems that offer computerized patient-tracking capabilities. More than 90% of New Hampshire radiologists exclusively use freehand dictation for reporting, and although almost 50% codify reports, only 11% use the American College of Radiology lexicon. These data and concerns expressed by radiologists, pathologists, technologists, and administrators helped shape the New Hampshire registry.

CONCLUSION. Heterogeneity of radiologic practices poses major challenges for implementing a population-based mammography registry. Issues such as confidentiality, the difficulty of assessing diagnostic acumen, and the time involved in providing data to a registry must be adequately addressed. For the registry to succeed in such diverse settings, researchers, radiologists, pathologists, technologists, and administrative staff must collaborate and cooperate.

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Development of a national mammography registry was proposed in 1989 as a way to enhance breast-screening effectiveness [1–5]. However, issues of confidentiality, accuracy, direct and indirect costs, and miscommunication erect practical barriers to implementing such a registry [2]. In an attempt to address these concerns, we report the results of an interview survey of radiologists, pathologists, mammography technologists, and administrative staff at mammographic facilities in New Hampshire. The findings from our survey have shaped the design and development of a statewide registry.

New Hampshire has an estimated population of 1,136,000, of whom 160,000 are women 40–74 years old [6]. About 37% of New Hampshire women between 40 and 49 years old report that they have not had a mammogram in the past 2 years, and 50% of women more than 50 years old report no mammogram in the past year [7].

The New Hampshire Mammography Network (NHMN) Project started in October

1994. Its purpose is to collect patient information (such as demographics and risk factors), interpretive results of mammograms, breast cancer staging information, initial treatment strategies, and mortality statistics for all women in New Hampshire who undergo mammography. The NHMN Project has two main objectives. The first is to assess the accuracy of mammography by comparing interpretive results with pathologic and tumor-registry reports. The second is to improve mammographic performance by reporting statewide aggregate data and facility-, radiologist-, and pathologist-specific data to facilities, radiologists, and pathologists. We also hope to use the registry as a resource for specific studies of breast cancer diagnosis, treatment, prognosis, and etiology.

The development phase of the NHMN Project involved the recruitment and survey of radiologists, pathologists, and mammographic facilities in New Hampshire. In the design phase, we implemented data collection strategies and attempted to address concerns of radiologists, pathologists, technologists, and administrators.

Materials and Methods

Radiologist and Pathologist Recruitment

In the grant application period, we sent letters to all radiology and pathology practices in New Hampshire, outlining the proposed project and soliciting suggestions. All 22 radiology practices and 14 pathology laboratories responded with letters supporting the proposed registry. We approached senior administrators from the New Hampshire State Tumor Registry and the New Hampshire Bureau of Vital Records and Health Statistics who agreed to participate. After funding was obtained, we discussed details of the project at the biannual meeting of the New Hampshire Radiological Society (American College of Radiology chapter). We solicited volunteers in October 1994 to serve on an advisory committee to the central research staff. The project was formally endorsed by both the New Hampshire Radiological Society and the New Hampshire Society of Pathologists. The institutional review board of the Dartmouth-Hitchcock Medical Center, the base of the registry, also gave approval. From radiologists and pathologists we obtained signed consent forms that outlined specifically what participation would involve and how data would be handled. This process clearly identified medical care professionals as human subjects whose confidentiality would be maintained. We also designed a consent form to provide confidentiality to participating women who undergo mammography in New Hampshire.

Facility Recruitment

As part of project development, either the NHMN Project director or the radiology liaison visited all 46 mammographic facilities in New Hampshire. The objective of each visit was to outline more fully what the project would involve; to enlist the support of radiologists, technologists, and pathologists; to determine the characteristics of each mammographic facility; and to identify and attempt to address potential concerns. Practice data were collected through structured interviews using a standardized questionnaire. All available radiologists from each practice, chief mammographic technologists of each facility, and, when possible, office managers, administrators, and pathologists participated in the interviews. Each visit, including briefly describing the project, collecting site-specific data, and addressing concerns of participants, took approximately 1 hr to complete.

Results

One center declined to provide site-specific information at the site visit; data presented here are based on information from the other 45 sites. Table 1 outlines the types of mammographic facilities and annual mammographic volumes. Because distinction between screening and diagnostic mammography is necessary to define test performance, we queried radiologists about how they made this determination. We found that 44% of facilities use patient self-report, 38% use the requisition from the referring physician, and in the remaining 18%, radiologists at the facilities make this distinction after the mammogram is interpreted. Only five (11%) facilities perform screening mammography exclusively.

Eighty-one (79%) of the 103 radiologists in New Hampshire interpret mammograms. Most of them practice in group associations with membership ranging between three and eight radiologists (mean, four radiologists). Few facilities provide clinical breast examinations (Table 2). Almost 60% perform breast sonograms, and almost half perform needle localization and sonographically guided cyst aspiration. Five perform stereotaxic core biopsies.

Although 71% of facilities in New Hampshire had computers (primarily DOS-based systems), most were used for billing purposes only (Table 3). Only 16% of facilities had radiology information systems or hospital information systems that would allow access to comprehensive patient information. Most radiologists generate mammographic reports using freehand dictation only, and few rely on computer-generated reports. At only four facilities do radiologists use the American College of Radiology (ACR) categories when codifying reports. However, radiologists generally agreed for project purposes to adopt the ACR lexicon and its assessment and recommendation terminology. Furthermore, these radiologists expressed enthusiasm for standardizing mammographic reporting in general.

We assessed how radiologists audit interpretive results of mammograms. After mammograms for which biopsy is recommended, all sites document pathologic results obtained at their institutions. Mammographic technologists obtain the pathologic results at 80% of facilities, and radiologists do so in the remaining 20%. Only 7% of facilities track the subsequent outcome of indeterminate or suspicious mammographic reports for which biopsy results are not readily available. Most audits are recorded manually (notebook or card file); only 4% of facilities use a computer system. Only 4% have a system to analyze the outcome of every mammographic encounter and to generate a statistical report. None of the facilities has the ability to rigorously track the outcome of negative mammograms because pathology

TABLE 1 Type of Facility, Representation in New Hampshire, and Mammographic Volume

Type of Facility	No. in New Hampshire (%)	Annual No. of Mammograms
Hospital-based	25 (54)	78,520
Clinic-based (hospital affiliate)	10 (22)	37,440
Private offices		
Radiologists	5 (11)	24,700
Nonradiologists	4 (9)	3,900
Women's health centers	1 (2)	2,800
Other	1 (2)	1,040

TABLE 2: Types of Services Provided at Mammography Facilities Participating in the Project (n = 45)

Services Provided	No. (%)
Clinical breast examinations	
Routinely provided	2 (4)
Provided to patients with symptoms	4 (9)
Breast sonography	26 (58)
Needle localization	22 (49)
Sonographically guided cyst aspiration	19 (42)
Stereotaxic core biopsies	5 (11)

TABLE 3: Computer Use and Reporting Methods at Mammography Facilities Participating in the Project (n = 45)

Computer Use and Reporting Methods	No. (%)
Type of computer	32 (71)
Macintosh	5 (16)[a]
DOS-based	27 (84)[a]
Radiology information system	7 (16)
Hospital information system	17 (38)
Methods of reporting	
Freehand dictation only	41 (91)
Computer generation only	1 (2)
Both	3 (7)
Category system	22 (49)
Site-specific	18 (82)
American College of Radiology	4 (18)
Patient tracking system	
Paper-based	41 (91)
Computer-based	4 (9)

[a] Percentages are based on the number of facilities that have computers (n = 32).

in such instances is available only when a patient is subsequently biopsied for a palpable abnormality at the same institution, or, in smaller communities, when the facility staff knows the patient.

We investigated notification processes by stratifying reports on the basis of the mammographer's degree of concern (Table 4). Few facilities have systems to remind patients or their primary care providers that routine mammograms are due. Only five facilities (11%) notify patients who are not self-referred of normal results. All facilities routinely contact the requesting physician when a biopsy is recommended.

TABLE 4: Methods of Notification Used by Mammographic Facilities in New Hampshire Mammography Network (n = 45)

Method of Notification	No. (%)
Routine mammogram	
Notifies patient or primary care provider that mammogram needs to be scheduled	7 (16)
Notifies patient of normal results by mail	5 (11)
Notifies primary care provider of normal results by mail	45 (100)
Abnormal mammogram	
Notifies primary care provider by mail	42 (93)
Notifies primary care provider by telephone	3 (7)
Notifies primary care provider by telephone and patient by mail	5 (11)
Biopsy recommendation	
Notifies primary care provider by telephone	26 (58)
Notifies primary care provider by mail	19 (42)

mostly by telephone. The number of radiologists who inform patients of results immediately after the mammogram was not collected.

Almost 40% of New Hampshire hospitals process, section, stain (standard hematoxylin and eosin), and diagnose breast specimens from surgery at their institutions. At 39% of New Hampshire hospitals, breast specimens from surgery are processed, sectioned, and stained at central off-site laboratories, and the slides are returned for diagnosis to the site of surgery. Rural New Hampshire hospitals have breast specimens that are surgically derived at their institutions processed and diagnosed at larger regional institutions. More than 70% of New Hampshire hospitals send fresh breast tumor tissue, when available, to out-of-state commercial laboratories for biochemical analysis of tumor-cell estrogen and progesterone-receptor protein. When diagnostic tissue is limited, paraffin-embedded tissue blocks are sent to the same out-of-state laboratories for immunohistochemical analysis. Almost 30% of New Hampshire hospitals send tissue blocks to a large regional medical center or a state laboratory for immunohistochemical analysis of tumor-cell estrogen and progesterone-receptor protein.

Staff Concerns at Mammographic Facilities

The most common concerns about participating in the NHMN Project included confidentiality of data (and attendant medicolegal implications), accuracy of data, and the direct and indirect costs of participation in the project.

Radiologists were universally concerned that participation in the project could expose their practices to damaging legal or public scrutiny. Some feared that plaintiff attorneys might gain access to the registry data and acquire the interpretive results of a particular radiologist in an attempt to show substandard care. Others were worried that collective (statewide) interpretive data might be used to establish standard-of-care norms, which would facilitate malpractice claims. Radiologists were specifically concerned that a lawyer might select data from a particular time range or community to establish a false standard that overestimated the accuracy of mammography. Lastly, some radiologists feared that data might be misused by a particular mammographic facility for marketing purposes. These same concerns were shared by office managers and administrators.

Concerning accuracy of data, radiologists wanted to be certain that data truly reflected their interpretive acumen. Both the accuracy of data entry and the statistical reliability of data were questioned. The issue of statistical reliability was a particular problem because chance alone could profoundly affect a specific radiologist's measures of screening performance if the case load was small.

We heard concerns about the additional work needed for data acquisition and management, and the cost of these services. Technologists worried that collecting patient data for the study would duplicate efforts already performed for site-specific patient-intake forms. Radiologists were concerned that even minimal time spent on each data entry could amount to a significant burden when handling large mammographic volumes. For example, if a radiologist interpretation form took 3 min to complete, then the interpretation of 30 mammograms a day would add 90 min of uncompensated time to each day.

Registry Design

Although the design of the registry was fully envisioned at the outset, specifics of data acquisition and implementation were

later influenced by the responses of personnel at mammographic facilities whom we met on our site visits. Clearly, the success of the registry depended on the cooperation and participation of mammographic facilities and radiologists. To ensure participation, the project was structured to include a central core of biomedical researchers and an advisory committee of community radiologists.

Because confidentiality of data was an overriding concern, we applied for protection of the database under a statute limiting access to data that are supplied by individuals and facilities for research purposes. Our application was reviewed, and we were authorized to access the legal protection that this statute allows.

New Hampshire facilities provide mammographic services to residents of Vermont, which also has a population-based mammography registry with state-specific legislation protecting confidentiality. We therefore reviewed appropriate mechanisms for protecting data passed across state lines, and we applied for a Federal Certificate of Confidentiality under Section 301(d) of the Public Health Service Act. We are working closely with Vermont to develop mechanisms for sharing data on patients who live in one state and receive services in the other, which we can implement once the Federal Certificate of Confidentiality has been granted.

In addition, both New Hampshire and Vermont are members of the National Cancer Institute–funded Breast Cancer Surveillance Consortium, which is a nine-member consortium with seven additional investigators from six other states (Colorado, California, Washington, Iowa, New Mexico, and North Carolina). The consortium has a statistical coordinating center that will assure both conformity and confidentiality of data for pooling purposes across all participating projects.

To address radiologists' concerns that data should truly reflect their interpretive acumen, we shared our proposed plans for data management, entry, and analysis. Participants were reassured to learn that manually entered interpretive data would be entered twice and checked for discrepancies. Any discrepancy will be brought to the attention of the data manager, who will resolve it by direct follow-up with individual mammographic facilities. To address the issue of how chance might affect statistical reliability in interpreting reports from our project, we chose to include confidence intervals in the analyses of data that are fed back to each site and each radiologist. If reports are based on few patients, the confidence interval will be wide.

To minimize the financial burden of providing data, we created a multipart system that requires primary input from four different sources. Data are provided separately by participating women, mammographic technologists, radiologists, and pathologists. Data from the New Hampshire State Tumor Registry on cancer incidence, staging, and initial treatment, as well as mortality data from the New Hampshire Bureau of Vital Records and Health Statistics, will be integrated at the central data repository.

The development of data-acquisition instruments for women, technologists, radiologists, and pathologists has been an iterative process that has occurred before and during pilot testing. All data forms have been developed with optical character recognition capability for data entry by scanner. The data are entered into a relational database that allows tracking by breast or by woman for each mammographic encounter.

The participant's form collects consent for participation, the patient's perception of why the mammogram is being done, assessment of health status, and demographic information. Obtaining active informed consent was deemed necessary by our institutional review board because medical records will be accessed for follow-up purposes. Most women take 3–7 min to complete the participant's form.

During the design phase, we responded to technologists' concerns about duplication of effort by incorporating each site's intake data into the technologist's form, using a one-copy no-carbon format. The copy is kept with the patient's record, and the original is sent to the central data repository. On this form, technologists collect information on current breast symptoms and hormonal status, surgical history of the breasts, and breast cancer risk factors. The form, which takes approximately 3 min to complete, replaces similar forms that facilities use, resulting in a standardization of data in patients' charts. This form was simplified by putting all negative responses along the left margin of the page. This way, data entry flows directly downward for women who are asymptomatic and have no breast surgical history or breast cancer risk factors.

On the radiologist's form, the radiologist notes indications for the examination and breast composition and makes an assessment and recommendation on the basis of the American College of Radiology lexicon. The form tracks data by breast and takes approximately 10 sec to complete for normal mammograms (about 85–90% of mammograms in the pilot test). To decrease completion time, the form lists indications, assessment, and recommendations for both breasts along the left border of the form, so data entry flows directly downward for normal mammograms.

Breast pathology reports (benign and malignant) throughout New Hampshire will be standardized, allowing data extraction at the central data repository. For all current breast specimens, data collection will include breast side, specimen type, and a diagnostic interpretation that details the presence of microcalcifications when appropriate. For malignant lesions, additional information to be collected will include tumor type, grade, and size; presence or absence of angiolymphatic invasion; tumor involvement in the skin, surgical resection margins, and local lymph nodes; the status of estrogen- and progesterone-receptor protein; and cell cycle analysis.

Status of the Registry

To date, 2406 mammogram reports have been provided to the registry by three pilot site facilities. Since our pilot start date in August 1995, levels of completeness of data have risen from 80% to 95%. We use simple status-report cards to inform facilities about completeness of incoming data. Missing data are successfully captured with a simple follow-up system. Of the 48 biopsy recommendations that are being tracked, 15 have come through the pathology system, of which seven have been malignant. We are also following 43 women whose mammograms have been assessed as highly suggestive of malignancy as well as 241 assessed as probably benign. Almost 95% of the women coming to these facilities have consented to be a part of this project, indicating acceptance by the public. After final testing of the data collection procedures, the remaining sites will join in the project. Copies of our data collection forms are available on request.

We have begun investigating computerized mammography management systems that are commercially available as well as several that are in development. Essential features include identifying and demographic data, risk factors, mammographic encounter

history, breast surgery history, current breast symptoms, mammography reporting information described with the ACR lexicon, ease of use, affordability, and ability to export data. We have also identified several nonessential features that would be of practical value to the participating mammographic facilities. These features include generation of patient and physician correspondence, the ability to word process dictated reports, the ability to construct reports on the basis of findings present, construction of pathology data fields, and the ability to manage records from multiple mammography sites from a central computer.

We anticipate that many of the high-volume sites may adopt a computerized mammography management system that will encode technologist and radiologist variables and periodically download these data to our centralized database. We hope to offer a system customized to meet the needs of the project as well as the individual sites at a reduced rate. In this customized system, data entry screens on computers would match those on our paper forms.

The concept of offering a computerized mammography management system appeals to personnel at facilities from many perspectives. Such a system allows each facility to act autonomously in the collection and maintenance of interpretive data while capturing more data and decreasing expense for ongoing data acquisition. Accuracy of computerized data entry remains an issue because the project's computer system does not allow double data-entry checks that are often part of a manual registry.

Radiologists were reassured to learn that their recording of interpretations would take less than 1 min and only about 10 sec for 85–95% of interpretations. In addition, we informed facility administrators that both paper-based and computer-assisted data collection options would be available. Many facilities have become particularly interested in computerized systems to limit the handling of multiple paper data collection forms and to facilitate internal interpretive audits of their practices. No matter what the data collection process, however, the project will always lack information on patients who live out of state or refuse to participate.

Discussion

The NHMN Project shares some of the goals described by Osuch et al. [4] in their proposal for a national mammography database, but our project differs in important ways. We hope to provide an objective assessment of the role of mammography in breast cancer outcomes, and we aspire to improve the accuracy of mammography through a feedback mechanism. One of the major goals of our registry is to create a resource that can be used by health researchers to further our understanding of breast cancer. This objective has not been emphasized in the literature, but we feel it is a critical part of the creation of any mammography database. Though our registry does not assume responsibility for ensuring timely and appropriate patient care, it will monitor long-term outcomes of women receiving mammography.

Many of the criticisms of a national mammography database raised by Taylor and Tocino [5] have been addressed in the development of the NHMN Project, but others present ongoing challenges. Funding has been partly addressed. We were fortunate to receive federal assistance to create the database and to support the central staff. We hope to configure this registry so that once it is functional, it will require minimal funding to maintain. The cost to facilities to participate in this program is difficult to quantify. Clark et al. [8], reporting on the Lee County, FL, mammography registry experience, estimated direct annualized costs of $1.75 for each mammographic report entered, an additional $3936 for each mammography facility, and an additional $1346 for each radiologist. However, no estimate of the indirect costs accrued by the facility and radiology practice was given. The radiology practices we surveyed all appear to operate with only the staff required to perform day-to-day functions: extra time spent on data collection for the project would result in significant expense to the mammographic facility and the radiology practice.

Thus far, participants have willingly given their time without financial compensation. We believe that this support will continue, mostly because the physicians and staff that run mammography facilities have a genuine interest in improving the services they provide. They also aspire to reduce the morbidity and mortality of patients with breast cancer. However, other incentives contribute to their willingness to participate. Many radiologists view participation as a way to satisfy the audit requirements of the Mammography Quality Standards Act of 1992 as administered by the Food and Drug Administration, to gain a more complete understanding of patient-tracking issues, and to measure performance against that of their peers. Also, most mammographers have a strong desire to know how many of their patients with negative mammograms go on to develop breast cancer, a statistic that now is only speculative. We realize that we are in the pilot phase of the project and that enthusiasm may wax and wane as the project progresses, but the fear that the mammography community will be unwilling to participate appears to be unfounded.

The need to standardize mammography and breast pathology reporting is being addressed continually as the project evolves. Our registry follows the ACR lexicon, but it allows radiologists to report on mammograms as they choose. In settings with computerized data acquisition and transcription, this may change, and adoption of the ACR lexicon may become mandatory. We found that most radiologists would be willing to change their reporting methods to comply with the language of the ACR lexicon. Also, we have commitments from all New Hampshire pathologists but one to standardize breast pathology reports.

Taylor and Tocino [5] suggested that a 1-year follow-up period is too soon to detect mammographically occult lesions, which leads to underestimation of the false-negative rate of mammography. We plan to provide statistical analyses that use both 1- and 2-year follow-up periods.

The medicolegal implications of a mammography registry are extensive. We have employed several strategies to protect participants from unnecessary risk, but action at the national level will be required to satisfy all the concerns of participants. We hope that the development of this and other registries will help stimulate federal legislation.

The benefits of a population-based mammography registry include improving the interpretive quality of mammography and improving the follow-up of patients with mammographic abnormalities [4]. We may also further our understanding of breast cancer, including the process of care and the natural history of this disease.

The challenge to implement complex data collection and tracking strategies among mammographic facilities with different organizational structures and staffs who handle high patient volumes is considerable. Meeting quality standards and addressing concerns about confidentiality, accuracy,

and cost are also daunting requirements. Because developing a national or regional registry means merging a clinical perspective with a public health perspective, success will not be achieved without considering the needs of mammography centers and understanding how they operate.

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The reader's attention is directed to the commentary on this article, which appears on the following pages.

Commentary

Mammography Outcomes Analysis: Potential Panacea or Pandora's Box?

Michael N. Linver [1], Robert D. Rosenberg [2], Robert A. Smith [3]

The demonstration of breast cancer mortality reduction through screening mammography in clinical trials was followed by a dramatic increase in screening mammography in the 1980s. During this period, numerous technical improvements enhanced image quality. Beginning in 1987, the American College of Radiology Mammography Accreditation Program encouraged this process, while growing public concern about breast cancer and mammography added even greater incentives to improve image quality. In 1992, the Mammography Quality Standards Act [1] mandated many of these measures and others regarding quality. No imaging procedure has been the focus of so much public and regulatory attention as mammography. Although this process challenges traditional medical autonomy, the net effect has been a discernible improvement in quality.

Although mammography image quality was the initial focus, mammography effectiveness has now attracted renewed interest. Analysis of breast cancer outcome in women undergoing screening mammography is a technique that received attention from Carney et al. [2] as a means to address this question, with the medical audit and population-based mammography registry as their major tools.

Background of the New Hampshire Mammography Network (NHMN)

As outlined in their paper [2], the authors established the NHMN on the basis of outcome review and population-based data collection. Outcome review evaluates the success of a process in reaching an important goal such as accurate cancer detection or exclusion. Population-based data collection is a relatively new technique for mammography research in the United States [3] but has been used for over 25 years in the Surveillance Epidemiology and End Results program of regional cancer registries to estimate national cancer trends in incidence and survival. The methods described by the authors in New Hampshire follow the model of Clark et al. [3], combining the data of mammography results with cancer registry data to assess performance of mammography (sensitivity and specificity) and effectiveness of mammography (cancer stage and size).

Interest in this methodologic approach was a motivating factor in the development of the International Breast Cancer Screening Database project, a voluntary international collaborative effort initiated in 1988. The intent of the project was to develop a process to allow comparisons among international programs. These standardized definitions, rules, and forms were the basis for common data collection in the population-based programs in the United States. In 1991, pilot projects started in Albuquerque and Detroit, and similar projects began independently in Florida and Colorado. From 1993 to 1995, the National Cancer Institute and the Department of Defense funded several regional efforts.

Most of these programs have now been organized by the National Cancer Institute into the Breast Cancer Surveillance Consortium, whose goal is to gather the same data items from diverse geographic and ethnic populations. This consortium will be performing pooled data analysis to examine general questions, and each group will pursue independent research projects and other analyses. These groups are operating in San Francisco, Colorado, New Mexico, Iowa, North Carolina, Vermont, New Hampshire, and two areas of Seattle. The total population of screening-age women in all of these projects is more than 1,000,000, with a cancer rate of at least 3700 per year. Unlike most research in radiology, this project focuses on community practice.

This article is a commentary on the preceding article by Carney et al.

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The article by Carney et al. [2] provides useful and timely information about mammography data collection by community radiologists, and it is also significant in describing population-based research. It shows that radiologists in the community are willing to freely share their experiences and results to better understand medical care, the diagnostic process, and the efficacy of screening mammography in their communities. Further, it finds radiologists are concerned about the appropriate use of this information and will usually participate only when the data are protected and used as intended. The article's research findings describe the use of two important procedures in mammography practice: categorizing results and tracking patients with abnormal results.

If the NHMN results are representative, approximately half of radiologists now use a system to code their mammography results into discrete categories. This finding shows how quickly the radiology community responds to trends. The use of standardized categories of mammography results is new: the initial Breast Imaging Reporting and Data System codes for results were first published in 1993 and revised in 1995 [4], with few groups using computers to generate reports and collect categorized results data before that time. Additionally, NHMN found that all surveyed radiology groups in New Hampshire regularly track abnormal mammogram results, which is a substantial increase from the 42% reported in a 1994 national survey by Brown and Houn [5] and is likely attributable to the Mammography Quality Standards Act requirement of patient tracking.

Relevance to Radiologists Today

Carney et al. [2] raise several issues that are of immediate relevance to all mammographers. First, radiologists appear to be willing to use the required coding for mammography reports to allow community-wide data collection. Second, if the trend toward discrete coding of results continues, it will soon become the standard for all radiologists. This trend enhances the potential for community-based surveillance, and it has the more important advantage of assuring clear communication of results among the radiologist, referring physician, and patient.

However, a third issue casts a shadow over the potential benefits for data collection offered by standardized reporting. The confidentiality of audit data must be assured if widespread sharing of these data is to occur. Concern over confidentiality applies not only to community data collection but also to audits done independently by each radiology group. If legal protection of data provided by medical audit is not available, radiologists will be faced with the difficult decision of whether to perform self analysis. Therefore, they and the community lose the opportunity to benefit from this important evaluation.

Radiologists' concerns that audit data be protected from disclosure are well justified. These data will be difficult to evaluate in many circumstances: small or unique screening populations may lead to audit outcomes that are biased toward apparently favorable or unfavorable results. The release of misleading raw outcome data for cardiac surgery patients has already occurred, and initially, these data were not corrected for any relevant differences among surgery centers. A similar release of raw mammography data could create more confusion than useful information. Concern over such a possibility may prevent collection of these data to study trends in breast cancer detection outcomes and discourage radiologists from reviewing their results.

Future Relevance to Radiologists

If these and other issues such as program costs can be resolved and widespread data collection and analysis are effected, the radiologic community and the populace as a whole stand to reap many measurable benefits. Radiologists would see improved quality in their interpretations as a result of direct feedback from the audit process. Moreover, pooling data within each community would allow development of a range of performance standards achieved within that community. Finally, questions about the actual effectiveness of screening mammography in a community could receive more definitive answers. The effectiveness of mammography in reducing mortality from breast cancer is well established from clinical trials conducted in the United States and abroad. However, community-level surveillance systems are necessary to determine whether community mammography is meeting its full potential. Therefore, the benefit of surveillance systems such as the NHMN cannot be overemphasized.

Care must be taken when comparing an individual's audit data to any community standard. Whereas the pooled community audit numbers of several hundred cancers will be large enough to provide statistically valid estimates, audit numbers dependent on cancers (sensitivity and cancer stage) will be small for most individuals, with large statistical fluctuations between audit periods and among radiologists. Further compounding the problem of comparing audit results are the variations in age, cancer risk factors, symptomatology, and screening history in patient populations seen by individual radiologists. In addition, the degree and type of follow-up available to find false-negative mammograms will vary. Each of these factors can significantly alter outcome: in effect, the results for some audit data may depend as much on the nature of the population screened, the quality and extent of the follow-up, and random variation as on the quality of the mammography. Therefore, community radiologists will not be able to easily compare their individual data with the community standard of pooled data. Consequently, radiologists and others seeking to use these data for comparison purposes must exercise great caution. The real value to community radiologists in this audit process lies in tracking general trends in interpretation patterns (callback rates, biopsy frequency), tracking numbers and size of cancers found, and realizing the audit's teaching potential as a source of cases for careful review.

Summary

As a consequence of the demand for and perceived value of mammography outcomes analysis, collection of community-based mammography data by the NHMN and others has begun and is supported by the radiologists involved. Radiologists are increasing their use of standardized coding of report data necessary for clear communication and data collection but remain justifiably concerned about the confidentiality of these data. If stronger protection of these data is forthcoming, more radiologists will be encouraged to perform practice audits. The pooling of community-based data as exemplified by NHMN will create statistics that measure the actual practice of mammogra-

phy and estimate its impact on breast cancer. For individual radiologists, the audit process will improve their mammography skills through direct feedback of results and provide important information about their patterns of interpretation. Although this approach will create community standards, comparisons with such standards may be more applicable among various communities than among individual radiologists because of the statistical variation created by the relatively small numbers of cancers found by individual radiologists, the differences in populations served by these radiologists, and the variability in reproducing the audit by individuals or groups. Pooled community data, however, will still be useful to community radiologists as general standards toward which to strive.

We believe that medical audits offer important potential public health benefits for breast cancer control. Insofar as confidentiality issues cannot be effectively addressed by individual radiologists, institutions in a position to be advocates should immediately explore how legal underpinnings can be put in place to protect the audit process from disclosure. With such protection, the audit process may fulfill its potential for the radiologist's pivotal role in breast cancer control; without it, the process may prove to be a Pandora's box for the community radiologist.

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